Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

Supplement to: Cannon CP, Blazing MA, Giugliano RP, et al. Ezetimibe added to statin therapy after acute coronary syndromes. N Engl J Med 2015;372:2387-97. DOI: 10.1056/NEJMoa1410489

Ezetimibe Added to Statin Therapy following Acute Coronary Syndromes

Supplementary Appendix 1

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IMPROVE-IT Trial leadership and Investigators

Executive Committee: Representatives from Thrombolysis in Myocardial Infarction (TIMI), Duke Clinical Research Institute (DCRI), and Merck & Co., Inc. (Merck).

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Eugene Braunwald (Study Chairman), Christopher P. Cannon (Principal Investigator), Robert Giugliano (Co-Principal Investigator), Sabina Murphy (Statistician), Stephen Wiviott (CEC Chairman), Erin Bohula-May (Investigator), Amy McCagg (TIMI Sr. Project Director), Carolyn McCabe (TIMI Project Director; 2005-2010), Suzanne Morin (TIMI Project Director; 2011-2014), Christina Pelland (Project Manager), Marc Bonaca (Director of TIMI Safety Desk), Dayle Acquilano (TIMI Safety Manager), Cheryl Lowe (CEC Director), Kristen Mills (CEC Manager).

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Steering Committee Members and National Lead Investigators:
Members of the TIMI Study Group, Duke Clinical Research Institute, and Thomas Musliner and Andrew Tershakovec from Merck (non-voting), plus Enrique Gurfinkel* (Argentina; deceased), Philip Aylward* and Andrew Tonkin (Australia), Gerald Maurer* (Austria), Frans Van de Werf* (Belgium), Jose C. Nicolau* (Brazil), Pierre Theroux*, Jacques Genest, and Paul Armstrong (Canada), Ramon Corbalan* (Chile), Daniel Isaza* (Colombia), Jindrich Spinar* (Czech Republic), Peer Grande* (Denmark; 2005-2013), Juri Voitk* (Estonia), Antero Kesaniemi* (Finland), Jean-Pierre Bassand* and Michel Farnier (France), Harald Darius* (Germany), Matyas

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* National Lead Investigator

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Malignancy Consultant: Charles S. Fuchs, Dana Farber Cancer Institution, Boston, MA.

Economics and Quality of Life (EQOL): Daniel B. Mark and David Cohen.

Participating Enrolling Centers: Representatives from the 1158 enrolling centers in 39 participating countries. Centers are listed in order of enrollment contribution.

ARGENTINA (332 patients, 24 centers)
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AUSTRALIA (116 patients, 10 centers)
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AUSTRIA (249 patients, 16 centers)
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BELGIUM (249 patients, 19 centers)
National Lead Investigator: F. Van de Werf
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BRAZIL (423 patients, 34 centers)
National Lead Investigator: J.C. Nicolau
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CANADA (1107 patients, 65 centers)
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CHILE (152 patients, 9 centers)
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COLOMBIA (568 patients, 20 centers)
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CZECH REPUBLIC (371 patients, 22 centers)
National Lead Investigator: J. Spinar
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DENMARK (576 patients, 19 centers)
National Lead Investigator: P. Grande (2005-2013)
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ECUADOR (45 patients, 5 centers)
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ESTONIA (10 patients, 2 centers)
National Lead Investigator: J. Voitk
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FINLAND (342 patients, 17 centers)
National Lead Investigator: A. Kesaniemi
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FRANCE (286 patients, 28 centers)
National Lead Investigator: J-P. Bassand
F. Schiele, J. Bassand, N. Meneveau, C.H.U. de Besancon, Hopital Jean Minjoz, Besancon; M. Galinier, M. Jean, C.H.U. de Toulouse, Hopital de Rangueil, Toulouse; M. Martelet, J. Mouallem, CH de Langres, LANGRES; M. Elbaz, J. Puel, D. Carrié, C.H.U. de Toulouse, Hopital de Rangueil, Toulouse; D. Coisne, N. Varroud-Vial, C.H.U. de Poitiers, Cite Hospitaliere de la Mileterie, Poitiers; O. Jaboureck, J. J. Dujardin, F. Leroy, Centre Hospitalier de Douai, DOUAI; J. Mansourati, Hopital de la Cavale Blanche, Brest; F. Funck, P. Jourdain, N. Guillard, Centre Hospitalier Rene Dubos, Cergy Pontoise; F. Coviaux, A. Gay, Centre Hospitalier d'Armentieres, Armentieres; C. Dourmap-Collas, C. Froger-Bompas, F. Paillard, C.H.R.U. de Rennes. Hopital de Pontchaillou, Rennes; O. Tricot, Centre Hospitalier de Dunkerque, Dunkerque; I. Maquin-Mavier, J.L. Dubois-Rande, D. Pongas, A.P.H. Paris, Hopital Henri Mondor, Creteil; F. Delahaye, M. Ovize, L. Benyahya, Hospices civils de Lyon, Hopital Cardiovasculaire Louis Pradel, Bron; J. Bonnet, Hopital Haut-Leveque, Pessac; L. Belle, L. Mangin, B. Lafitte, Centre Hospitalier de la region d'Annecy, Metz-Tesy; G. Zemour, N. Doux, C.H. de Cannes, Cannes; B. Agraou, N. El Mansour, Centre Hospitalier, Valenciennes; G. Traisnel, M. El Jarroudi, Polyclinique du Bois, LILLE; P. Ohlmann, Nouvel Hopital Civil de Strasbourg, STRASBOURG; B. Diadema, M. Escande, Centre Hospitalier d'Allauch, Allauch; G. Legros, J.M. Demarcq, Y. Haftel, Centre Hospitalier Victor Provo, ROUBAIX; S. Alsagheer, P. Dambrine, Hopital S.S.M., Freyming Merlebach; Y. Cottin, Hopital du Bocage, C H U de Dijon, Dijon; S. Ghostine, C. Caussin, Centre Chirurgical Marie Lannelongue, Le Plessis-Robinson; A. Gacem, J.M. Bouvier, C.H.G. de Cholet, Cholet; J. Poulard, CH de Abbeville, Abbeville; J. Davy, C.H.U. de Montpellier, Hopital Arnaud De Villeneuve, Montpellier; A. Furber, F. Prunier, C.H.U. d'Angers, Hotel Dieu, Angers.

GERMANY (935 patients, 55 centers)
National Lead Investigator: H. Darius
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HONG KONG (58 patients, 2 centers)
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HUNGARY (116 patients, 15 centers)
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INDIA (260 patients, 23 centers)
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ISRAEL (655 patients, 26 centers)
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Weiss, D. Leibowitz, Hadassah Mount Scopus Medical Center, Jerusalem; R. Zimlichman, J. Ben-Aharon, Edith Wolfson Medical Center, Holon; H. Hammerman, R. Dragu, Rambam Medical Center, Haifa; Y. Rozenman, V. Witzling, Wolfson Medical Center, Holon; D. Tzivoni, M. Moriel, Shaare Zedek Medical Center, Jerusalem; A. Halkin, D. Sheps, N. Bogomolny, Tel-Aviv Sourask yMedical Center, Tel-Aviv; M. Mosseri, Y. Khudyak, Meir Medical Center, Kfar Saba; B. S. Lewis, S. Halabi, K. Uziel-Iunger, R. Yuval, Lady Davis Carmel Medical Center, Haifa; S. Shimoni, A. Caspi, S. Botwin, Kaplan Medical Center, Rehovot; D. Gavish, A. Sandler, Edith Wolfson Medical Center, Holon; A. Pollak, B. Kreisberg, Hadassah - Hebrew University Medical Centers, Jerusalem; O. Hussein, K. Abu Jabal, Ziv Medical Center, Safed; Y. Henkin, A. Grosbard, Soroka Medical Center, Beer Sheva; U. Rosenschein, E. Rivlin, Bnai Zion Medical Center, Haifa; D. Zeltser, N. Platner, Tel-Aviv Sourasky Medical Center, Tel-Aviv; A. Porter, N. Harel, Rabin Medical Center, Petach-Tikva; M. Lishner, A. Elis, M. Karny, Meir Medical Center, Kfar Saba; S. Fuchs, G. Y. Stein, Rabin Medical Center, Petach-Tikva; E. Grossman, Z. Gealel, Chaim Sheba Medical Center, Ramat Gan; F. Schlaeffer, I. Liberty, Soroka Medical Center, Beer Sheva; A. Golik, O. Tzuman, Assaf Harofe Medical Center, Be'er- Ya'akov.

ITALY (593 patients, 69 centers)
National Lead Investigator: G. M. De Ferrari
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MALAYSIA (59 patients, 4 centers)
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NETHERLANDS (1191 patients, 40 centers)
National Lead Investigators: T. Oude Ophuis and J. Wouton Jukema
E. van Nes, C.J.P.J Werter, Laurentius Ziekenhuis, Roermond; A.J.M. Oude Ophuis, Canisius-Wilhelmina Ziekenhuis, Nijmegen; R.P.Th. Troquay, VieCuri, Medisch Centrum voor Noord-Limburg, Venlo; B.J.B. Hamer, Meander Medisch Cenrum, Amersfoort; T. Lenderink, R.J.C.T. Feld, Atrium Medisch Centrum, Heerlen; M.W.J. van Hessen, E.P. Viergever, Groene Hart Ziekenhuis, Locatie Bleuland, Gouda; A. van der Sluis, D.J.A. Lok,E.A. Badings, Deventer Ziekenhuis, Deventer; P.R. Nierop, I.Y. Danse, Sint Franciscus Gasthuis, Rotterdam; W.R.M. Hermans, N.J. Holwerda, St. Elisabeth Ziekenhuis, Tilburg; H.J.M. Thijssen, L.J.H.J. Theunissen, Maxima Medisch Centrum Veldhoven, Veldhoven; C. van der Zwaan, Ziekenhuis Rivierenland, Tiel; B.J. Van Den Berg, I.H.G.M. Hendriks, IJsselland Ziekenhuis, Capelle aan de IJssel; E. Ronner, A.J.A.M. Withagen, A.H.J.M. Dijkshoorn-Giesen, Reinier de Graaf Gasthuis, Delft; J.P. Ezechiels, A.F.M. Kuijper, Spaarne Ziekenhuis, Hoofddorp; F.R. Den Hartog, P.M. Van Kalmthout, Ziekenhuis Gelderse Vallei, Ede; E.M. Buijs, M. van der Zeijst, Tergooi Ziekenhuis, locatie Blaricum, Blaricum; P.A.G. Zwart, J.A.M. Zuidgeest, Ziekenhuis Bernhoven, Oss; M. van Eck, M.C.G. Daniels, N. van der Ven-Elzebroek, Jeroen Bosch Ziekenhuis, Den Bosch; A. Van 't Hof, Isala, Zwolle; A.J. van Boven, A. van der Weerdt, Hartcentrum Friesland, MC Leeuwarden, Leeuwarden; P.H.J.M. Dunselman, M.A. Alings, Amphia Hospital Location Molengracht, Breda; R.F. van Es, S.H.K. The, Ziekenhuis Bethesda, Hoogeveen; C. Gurlek, A.H Liem, H.W.O. Roeters van Lennep, Admiraal De Ruyter Ziekenhuis, Goes; B. Van Vlies, C. Kalkman, Kennemer Gasthuis locatie Zuid, Haarlem; H.P. Swart, P. van der Bij, Antonius Ziekenhuis, Sneek; R. Taverne, R. Ciampricotti, C. van Dam, ZorgSaam ziekenhuis, Terneuzen; H. Spierenburg, I. van Ruijven, Vlietland Ziekenhuis, Schiedam; L.H.J. van Kempen, F.F. Willems, Ziekenhuis Rijnstate, Arnhem; A. Dirkali, I. Stoel, Albert Schweitzer Ziekenhuis, Dordrecht; J. Plomp, S. Veldmeijer, Tergooi Ziekenhuis, locatie Hilversum, Hilversum; G. Tjeerdsma, R. Nijmeijer, Ziekenhuis De Tjongerschans, Heerenveen; J.M.C. Van Hal, Slingeland Ziekenhuis, Doetinchem; G.L. Bartels, J.L. Posma, CRN, Martini Ziekenhuis, Groningen; G.C.M. Linssen, C.G.K.M.Fauser, Ziekenhuisgroep Twente, Almelo; R.A. Waalewijn, B.E. Groenemeijer, Gelre ziekenhuizen, Apeldoorn; L. Pos, J.H. Fast, H.T. Droste, Ziekenhuisgroep Twente, Hengelo; J. Westenburg, W. Veenstra, Scheper Ziekenhuis Emmen, Emmen; J. Koolen, Catharina Ziekenhuis, Eindhoven; L.W.H. van Loo, W. Smits, Maasziekenhuis Pantein, Boxmeer; J.G.J. Milhous, P. van Rossum, S. Stuij, Beatrix Ziekenhuis, Gorinchem.

NEW ZEALAND (164 patients, 8 centers)

National Lead Investigator: H. White
R. Scott, A.M. Richards, Z. Morrison, Lipid and Diabetes Research Group, Christchurch; G. Devlin, R. Fisher, Waikato Hospital, Hamilton; R. Stewart, J. Benetar, Auckland City Hospital, Auckland; J. Voss, S. Wong, D. Scott, Middlemore Hospital, Auckland; R. Luke, Hawkes Bay Hospital, Hastings, Hawkes Bay; E. W. Tang, L. Davidson, Palmerston North Hospital, Palmerston North; A. Hamer, S. Wilson, R. Price, Nelson Hospital, Nelson; H. Hart, A. Turner, North Shore Hospital, Auckland.

NORWAY (295 patients, 20 centers)
National Lead Investigator: T. Pedersen
J. Jortveit, S. Calic, T. Gundersen, H. Brunvand, L. Fosse, Soerlandet sykehus HF Arendal, Arendal; O. Nygaard, B. Gjellefall, Helse Bergen HF Haukeland Universitetssykehus, Bergen; S.A. Gravdal, R. Ringstad, Haraldsplass Diakonale sykehus AS, Bergen; D. Atar, H. Clausen, Oslo Universitetssykehus HF, Aker, Oslo; J. Hysing, K. Arvesen, M. Topper, E. Flagstad, Sykehuset Telemark HF, Skien; T. Graven, H.H. Haug, Helse Nord-Trondelag HF Sykehuset Levanger, Levanger; L. Dalin, R. Al-Ani, Sykehuset Oestfold Moss, Moss; J. E. Otterstad, K. Ausen, Sykehuset Vestfold HF, Toensberg; E. Aaser, M. Olufsen, Sykehuset Asker og Baerum HF, Rud; S. Halvorsen, H. Clausen, Oslo Universitetssykehus HF, Ullevål, Oslo; L. Gullestad, W. Stueflotten, Oslo Universitetssykehus HF, Rikshospitalet, Oslo; K. Waage, R.M. Stødle, Helse Fonna hf Haugesund sjukehus, Haugesund; C. Hall, O. Aase, J. Nordeng, E. Soyland, E.R. Fageraas, Ringerike Sykehus HF, Hoenefoss; A. Lied, R. Aske, Helse Nordmoere og Romsdal hf Molde, Molde; N. Raouf, J. Johansson, Sykehuset Oestfold Fredrikstad, Fredrikstad; T. Herrscher, E. Skogrand, Lovisenberg Diakonale Sykehus AS, Oslo; H. Bjornstad, I. Aagnes, B.I. Arntsen, Nordlandssykehuset hf, Bodoe; J. Vegsundvaag, M.E. Skjold, Helse Sunnmoere HF Aalesund sjukehus, Aalesund; H. Velle, M.B. Aambakk, Helse Sunnmoere HF Volda Sykehus, Volda; O. Skjetne, A. Byfuglien, Sykehuset Innlandet HF Gjoevik, Gjoevik.

PERU (65 patients, 13 centers)
National Lead Investigator: F. Britto
J. Rodriguez, D. Galvez, Santiago de Surco, Angela Pinto; F. Medina, H.A. Anchante Hernandez, San Martin de Porres, Jeanneth Patricia Rodriguez Lujan; V. Rodriguez Chavez, R. Morales, Miraflores, Nurys Cabanillas; E. Chavez Huapalla, D. Velasquez, Santiago de Surco, Alex Chaname; F. Torres, R. Morales, Lima Cercado, Alexandra Zavala; F. Britto, O. Aguirre, Jesus Maria, Magaly Cepeda ; L. Toce Yanez, M. Andrade, Lima, Cinthya Ballona; C. Campos, R. Arce, Bellavista, Olga Castillo; W. Mogrovejo, F. Osores, Miraflores, Juan de Dios Godoy; G. Bustamante, M. Rodriguez, San Borja, Isabel Marruffo; P. Berrospi, C. Garcia, San Isidro, Renzo Barbini; M. Zubiate Talledo, P. Rios Navarro, Jesus Maria, Jovanna Diestra; M. Horna, V. Herrera, Bellavista, Susana Delgado.

POLAND (589 patients, 30 centers)
National Lead Investigator: W. Ruzyllo
W. Ruzyllo, J. Kadziela, Instytut Kardiologii im.Prym.1000-lecia S.Kard. Wyszynskiego, Warszawa; A. Rybicka-Musialik, M. Trusz-Gluza, A. Berger-Kucza, Samodzielny Publiczny Szpital Kliniczny Nr 7, Katowice; W. Musial, A. Tycinska, Samodzielny Publiczny Szpital Kliniczny AM, Bialystok; R. Gil, A. Gziut, Centralny Szpital Kliniczny MSWiA w Warszawie, Warszawa; J. Gorny, M. Tyllo, SP ZOZ Wojewodzki Szpital Specjalistyczny w Olsztynie, Olsztyn; Z. Reszka, M. Mickiewicz-Pawlowska, Wojewodzki Szpital Zespolony, Elblag; B. Wrzosek, J. Kosior, Wojewodzki Szpital Specjalistyczny, Radom; P. Staneta, R. Korzeniak, Specjalistyczna Przychodnia Lekarska "MEDIKARD", Plock; Z. Kalarus, E. Markowicz, Slaskie Centrum Chorob Serca w Zabrzu, Zabrze; P. Miekus, M. Konarzewski, Gabinet Kardiologiczny Medipuls, Gdynia; A. Kleinrok, M. Puzniak, Samodzielny Publiczny Szpital Wojewodzki im. Papieza Jana Pawla II, Zamosc; S. Grajek, M. Janus, I Klinika Kardiologii UM w Poznaniu, Poznan; M. Krzyzanowski, A. Hoffmann, P. Muzalewski, NZOZ Przychodnia "Lomzynska", Bydgoszcz; L. Polonski, A. Kazik, Slaskie Centrum Chorob Serca w Zabrzu, Zabrze; E. Nowalany-Kozielska, C. Wojciechowska, Szpital Specjalistyczny w Zabrzu, Zabrze; P. Ponikowski, S. Nawrocka, 4 Wojskowy Szpital Kliniczny z Poliklinika SP ZOZ, Wroclaw; K. Filipiak, A. Serafin, Samodzielny Publiczny Centralny Szpital Kliniczny w Warszawie, Warszawa; J. Dubiel, W. Mielecki, Szpital Uniwersytecki w Krakowie, Krakow; M. Ogorek, D. Kopcik, SP ZOZ Samodzielny Szpital Wojewodzki im. Mikolaja Kopernika, Piotrkow Trybunalski; K. Jaworska, G. Skonieczny, Wojewodzki Szpital Zespolony im. L. Rydygiera w Toruniu, Torun; K. Kawecka-Jaszcz, L. Bryniarski, SP ZOZ Szpital Uniwersytecki w

Krakowie, Krakow; W. Tracz, A. Lesniak-Sobelga, Krakowski Szpital Specjalistyczny im. Jana Pawla II, Krakow; J. Jankielewicz, R. Zaluska, Samodzielny ZP ZOZ im. Dr J. Psarskiego, Ostroleka; R. Trojnar, P. Kawalek, Specjalistyczny Gabinet Kardiologiczny i Internistyczny, Lublin; Z. Gaciong, J. Piotr Samodzielny Publiczny Centralny Szpital Kliniczny w Warszawie, Warszawa; G. Pulkowski, M. Anaszewicz, Szpital Uniwersytecki nr 2 im. dr Jana Biziela w Bydgoszczy, Bydgoszez; W. Samul, J. Adamus, M. Cholewa, L. Kubik, R. Szczechowicz, Wojskowy Instytut Medyczny, Warszawa; J. Rekosz, D. Kwiatkowska, Stacja Pogotowia Ratunkowego i transportu sanitarnego Meditrans, Warszawa; J. Gajek, W. Mazurek, Jacek Jerzy Gajek Prywatna Praktyka Lekarska, Wroclaw; M. Kominek, T. Siminiak, E. Guzniczak, Szpital Rehabilitacyjno-Kardiologiczny w Kowanowku, Kowanowko k. Obornik Wlkp.

PORTUGAL (102 patients, 13 centers)
National Lead Investigator: M. Carrageta
P. Monteiro, L. Providencia, S. Monteiro, Hospitais da Universidade de Coimbra, Coimbra; T. Pinho, C. Gavina, C. Sousa, Hospital de Sao Joao, E.P.E., Porto; J. Loureiro, A.R. Ferreira, Hospital Prof. Dr. Fernando da Fonseca, E.P.E., Amadora; A. Almada Cardoso, J. Rodrigues Araujo, I. Rebolo, Servico de Saude da Regiao Autonoma da Madeira, E.P.E. - Hospital Central do Funchal, Funchal; C. Catarino, M. Carrageta, Hospital Garcia de Orta, EPE, Almada; J. Oliveira Santos, L.P. Nunes, Hospital de Sao Teotonio, E.P.E., Viseu; J. Mimoso, N. Marques, Hospital de Faro, Faro; M. A. Leitao J. Pais, A. Fernandes, Centro Hospitalar de Coimbra, E.P.E., Coimbra; A. Nunes Diogo, J. Nóbrega, Hospital de Santa Maria, E.P.E., Lisbon; J.I. Azevedo Moreira, P. Mateus, Centro Hospitalar de Tras-os-Montes e Alto Douro, E.P.E., Vila Real; J. Oliveira, M. Selas, Centro Hospitalar de Lisboa Central, E.P.E., Hospital de Santa Marta, Lisboa; V. Ribeiro, A. Albuquerque, Centro Hospitalar de Vila Nova de Gaia, Vila Nova de Gaia; R. Palma Reis, A. Ramos, F. Salazar, Centro Hospitalar Lisboa Norte, E.P.E. - Hospital Pulido Valente, Lisboa.

SINGAPORE (75 patients, 2 centers)
D. Nair, C.K. Ng, D. Yeo, Tan Tock Seng Hospital, Singapore; A. Wong, National Heart Centre - Department of Cardiology, Singapore.

SLOVAKIA (121 patients, 13 centers)
National Lead Investigator: T. Duris
S. Funiak, M. Belicova, MFN, Martin; I. Striezova, P. Krajci, K2 Med s.r.o., Banska Bystrica; G. Sojka, KARDIO-ANGIO, s.r.o, Levice; O. Herman, A. Zemberova, Fakultna nemocnica Trencin, Trencin; D. Pella, J. Fedacko, CARDIO D&R spol. s.r.o. Kosice, Kosice; A. Banikova, K. Micko, Kardiomed s.r.o., Lucenec; V. Macek, FN Trnava, Trnava; M. Moscovic, VUSCH Kosice, Kosice; P. Vahala, T. Vykoukalova, Kardiocentrum Nitra s.r.o., Nitra; T. Duris, MUDr. Tibor Duris CSc, s.r.o., Nove Zamky; A. Dzupina, M. Marusakova, ALIAN s.r.o., Bardejov; J. Stevlik, E. Akubzanova, Univerzitna nemocnica Bratislava, Bratislava; K. Hatalova, Cardioconsult s.r.o., Bratislava.

SOUTH AFRICA (186 patients, 17 centers)
National Lead Investigator: A. Dalby
L. Burgess, C. Coetzee, TREAD Research cc, Parow; T. Mabin, J. Roos, J. Roos, Vergelegen Medi-Clinic, Somerset West; Z. Mohamed, T. Pillay, Vincent Pallotti Hospital, Cape Town; C. Corbett, W. Bodenstein, Panorama Medi-Clinic, Cape Town; F. Tayob, St Augustines Hospital, Glenwood, Durban; I. Ebrahim, C. Bolsman, Unitas Hospital, Centurion; A. Horak, E. Lloyd, Vincent Pallotti Hospital, Cape Town; M. Pretorius, Tiervlei Trial Centre, Bellville; P. Commerford, M. De Andrade, E17 New Groote Schuur Hospital, Obsevatory Cape Town; J. Roux, A. Murray, Panorama Medi-Clinic, Panorama, Cape Town; P. Soma, E. Delport, Clinical Research Unit, University of Pretoria, Pretoria; A. Dalby, G. Cassel, Milpark Hospital, Johannesburg; L. Van Zyl T. Cronje, Clinical Projects Research Trial Centre, Worcester; M. Sarvan, R. Moodley, Dr MI Sarvan,R Moodley and Partners INC., Tongaat; M. Guerra, N. Swanepoel, Syzygy Clinical Research , Pretoria; J. Bayat, Dr. J. Bayat, Durban; E. Klug, S. Hellig, Sunward Park Hospital, Boksburg.

SOUTH KOREA (118 patients, 12 centers)
National Lead Investigator: K-B. Seung

J. Yoon, J. Kim, Wonju Severance Christian Hospital , Wonju; W. Chung, Y. Choi, Yeouido St. Mary Hospital, Seoul; M. Cho, S. Lee, Chungbuk National University Hospital, Cheongju; H. Moon Kwon, B. Hong, Yonsei University Gangnam Severance Hospital, Seoul; K. Seung, K. Chang, Seoul St. Mary's Hospital, Seoul; S. Rha, Korea University Guro Hospital, Seoul; M.H. Jeong, Y. Hong, Chonnam National University Hospital , Gwangju; C. Lee, Asan Medical Center, Seoul; I. Seong, J. Jeong, Chungnam National University Hospital, Daejeon; S. Tahk, M. Yoon, Ajou University Hospital, Suwon; S.C. Chae, Kyungpook National University Hospital (KNUH), Daegu; H. Kim, Seoul National University Hospital , Seoul.

SPAIN (551 patient, 38 centers)
National Lead Investigator: J. Lopez-Sendon
V. Lopez, J.M. González Roldan, Hospital Universitario Virgen de la Macarena, Sevilla; P. Mancisidor, P. Mancisidor, J. Froufe, A. Martín López, Hospital de Cruces, Baracaldo; S. Nicolas Franco A. Ros Molina, Hospital Rafael Mendez, Lorca; F. Ridocci Soriano, Hospital General Universitario de Valencia, Valencia; M. Cobos, H.D. Mejía, Hospital Clinico San Carlos, Madrid; R. Rubio Sanz, A. Vazquez, Hospital Gregorio Maranon, Madrid; F. Sogorb Garri, I. Arrarte Esteban, Hospital Universitario de Alicante, Alicante; P. Marco, J. J. Artaecheverria, Hospital de Donostia, Donostia; A. Cequier, E. Esplugas, J. Gonzalez, Ciutat Sanitaria de Bellvitge, L'Hospitalet de Llobregat; E. Lopez de Sa E. Armada, Hospital La Paz, Madrid; F. Worner, I. Hernández, Hospital Arnau de Vilanova de Lleida, Lerida; F. Roncales, J. Gomollon, A. del Rio,J. Alameda, Hospital Clinico Lozano Blesa, Zaragoza; E. Galve Basilio, M. Velat Rafols, Hospital Vall d'Hebron, Barcelona; M. Vida Gutierrez, R. Martos Ferres, Complejo Hospitalario de Torrecardenas, Almeria; C. Molla, J. Antón Pascual, Hospital Sant Joan de Alicante, Sant Joan; J. Bruguera Cortada, C. García, Hospital del Mar, Barcelona; G. Iglesias, E. Villa, Hospital Central de Asturias, Oviedo; F. Aros, Hospital de Txagorritxu, Vitoria; I. Lekuona Goya, M. Morillas Bueno, Hospital de Galdacano, Galdacano; R. Vicho Pereira X. Montero Clavero, C.D. Corradini Pasaron, Clinica Palmaplanas, Palma de Mallorca; R. Jorda, R. Vicho Pereira, O. Perez, Clinica Rotger, Palma de Mallorca; E. de Teresa, M. Jimenez Navarro, Hospital Virgen de la Victoria (Cardiology), Malaga; F. de la Guia, F. de la Guia, T. Lozano, I. Antorrena, M. López Aranda, Hospital Marina Baixa, Villajoyosa; L. Alonso, J. Gonzalez Mirelis, Hospital Puerta de Hierro de Majadahonda, Majadahonda; S. Alcasena, V.A. Paniagua, Hospital de Navarra, Pamplona; J. Gonzalez Juanatey, L. Gregorian, Hospital Santiago de Compostela, Santiago de Compostela; J. Munoz, A. Llacer Escorihuela, Hospital Clinico de Valencia, Valencia; A. Salvador Sanz, A. Flores, Hospital La Fe de Valencia, Valencia; P. Alvarez Garcia M. Rodriguez Rodriguez, Hospital de Viladecans, Viladecans; F. Alfonso, E. Marin, A. Lozano, Hospital La Princesa, Madrid; A. Bethencourt, A. Grau, Hospital Son Dureta (Hospital Son Espases), Palma de Mallorca; A. Martinez Rubio J. Punti Sala, Hospital de Sabadell, Sabadell; N. Royuela, J. San Jose, V. Bugos, H. Marques de Valdecilla, Santander; J. Alonso Martin R. Jimenez, Hospital Universitario de Fuenlabrada, Fuenlabrada; M. Sieres Felgueres, Hospital de Cabuenes, Gijon; P. Vigil Escalera, Hospital de Cabuenes, Gijon; R. Campuzano Ruiz L. Lopez Bescos, I. Monedero Sanchez, Fundacion Hospital Alcorcon, Alcorcon; M. Valdes Chavarri, Hospital de la Arrixaca, El Palmar; G. Casares, Hospital San Agustin, Aviles.

SWEDEN (480 patients, 24 centers)
National Lead Investigator: M. Dellborg
M. Dellborg, P. Johanson, G. Hultsberg-Olsson, Sahlgrenska Universitetssjukhuset / Ostra, Goteborg; N. Witt, B. Samad, T. Damm, Sodersjukhuset, Stockholm; M. Risenfors, L. Ortgren, Sahlgrenska Universitetssjukhuset Molndal, Mölndal; L. Henareh, T. Jernberg, M. Berglund, Karolinska Universitetssjukhuset Huddinge, Stockholm; J. Karlsson, A. Koch, Lanssjukhuset Ryhov, Jönköping; M. Lycksell, C. Lundgren, Sundsvall Lanssjukhuset, Sundsvall; J. Herlitz, M. Sjölin, Sahlgrenska Universitetssjukhuset, Göteborg; D. Erlinge, E. Matson, Skånes Universitetssjukhus, Lund, Lund; S. Cizinsky, F. Carlsson, B. Ryttberg, K. Johansson, Orebro Universitetssjukhus, Örebro; H. Tygesen, J. Bergsten, Sodra Alvsborgs Sjukhus Boras, Borås; U. Naslund, C. Sundholm, Norrlands Universitetssjukhus, Umeå; I. Timberg, P. Wikström, Hassleholms Sjukhus, Hässleholm; P. Hårdhammar, A. Lisbeth, Hallands sjukhus Halmstad, Halmstad; L. Lund, C. Hage, Karolinska Universitetssjukhuset Solna, Stockholm; U. Rosenqvist, M. Gründås, Motala Lasarett, Motala; L. Larsson, A. Hammerman, Vasterviks sjukhus, Västervik; G. Andersson, S. Johansson, Vaxjo Centrallasarett, Vaxjo; M. Bennermo, H. Tjerneld, Danderyds Sjukhus, Stockholm; M. Forsgren, K. Eriksson, Falu Lasarett, Falun; M. Eriksson,

P.O. Bengtsson, W. Yu, K. Ceder-Brolin, Capio St. Gorans Sjukhus, Stockholm; C. Stafberg, E. Andersson, Enkoping Lasarett, Enkoping; V. Roussine, K. Ångman, B. Melin, Hudiksvalls sjukhus, Hudiksvall; S. Thorsen, L. Lundell, Helsingborgs lasarett, Helsingborg; F. Buijs, S. Östberg, Mora Lasarett, Mora.

SWITZERLAND (265 patients, 12 centers)
National Lead Investigator: F. Mach
F. Mach, P. Sigaud, Hôpitaux Universitaires de Genève, Genève; T. Moccetti, M. Bondio, Cardiocentro Ticino, Lugano; V. Kuehlkamp, M. Pieper, Herzzentrum Kreuzlingen, Kreuzlingen; A. Gallino, Ospedale San Giovanni, Bellinzona; H. Zender, D. Genné, J. Gauthey, Hôpital Neuchâtelois, La Chaux-de-Fonds; M. Wilhelm, H. Saner, L. Trachsel, Inselspital, Bern; C. Roethlisberger, H. Schlaepfer, T. Kujawski, Spitalzentrum Biel, Biel; A. Pagnamenta, Ospedale Regionale di Mendrisio, Mendrisio; S. Meyer-Monard, R. Krapf, B. Biedermann, H. Schneider, Kantonsspital Baselland, Bruderholz; H. Rickli, Kantonsspital St. Gallen, St. Gallen; D. Ramsay, Kantonsspital Zug, Baar; A. Linka, P. Ballmer, M. Wegmann Oswald, Kantonsspital Winterthur, Winterthur; G. Girod, Hôpital de Sion, Sion.

TAIWAN (46 patients, 6 centers)
M. Charng, H. Shu-Ling, Taipei Veterans General Hospital, Taipei; K. Chang, L. Ping-Han, China Medical University Hospital, Taichung; C. Wu, S. Liu, Chang Gung Memorial Hospital, Kaohsiung Branch, Kaohsiung; M. Lin, W. Chian-Yi, National Taiwan University Hospital, Taipei; H. Yeh, C. Mei-Juan, Mackay Memorial Hospital-Tamshui Branch, Taipei; I. Hsieh, Y. Wang, Chang Gung Memorial Hospital - Linkou, Taoyuan County.

TURKEY (50 patients, 7 centers)
National Lead Investigator: S. Guneri
E. Ural, T. Sahin, Kocaeli Universitesi Tip Fakultesi, Kocaeli; S. Guneri, Z. Yildiz, Dokuz Eylul Universitesi Tip Fakultesi, Izmir; M. Kayikcioglu, H. Kultursay, Ege Universitesi Tip Fakultesi, Izmir; Z. Yigit, I. Calpar, Istanbul Universitesi Kardiyoloji Enstitusu, Istanbul; N. Ata, O. Goktekin, U. Senol, Osmangazi Universitesi Tip Fakultesi, Eskisehir; R. Yalcin, T. Timurkaynak, U. Kaya, Gazi Universitesi Tip Fakultesi, Ankara; A. Yildirir, E. Karacaglar, Baskent Universitesi Tip Fakultesi, Ankara.

UKRAINE (159 patients, 16 centers)
National Lead Investigator: A. Parkhomenko
A. Faynyk, M. Sorokivskyy, L'viv Reg State Clin Treatment-and-Diagnostic Cardiology Center, L'viv; O. Koval, P. Kaplan, MI "DCJE Hosp" of Dnipropetrovsk Regional Council" Cardiology dep#2 . SI "DMAo of MoH of Ukraine", Dnipropetrovs k; I. Kraiz, K. Popova, STPI "Central Clinical Hospital of Ukrzaliznytsya", Kharkiv; Y. Kyyak, O. Barnett, L'vivClinCity Hospital of Emerg MedCare, MI dep. Halytsky NMU,dep of fam.med, L'viv; O. Karpenko, L. Todoriuk, Kyiv City Clinical Hospital No.1, Kyiv; V. Tseluyko, K. Sergiy MI of HC"Kharkiv City Clinical Hospital #8". Dep of Cardiol. KhMAPE. Dep of Cardiol. & Functional Diagn., Kharkiv; M. Kopytsya, O. Petyunina, GI "L.T.Malaya Therapy Institute of the NAMS of Ukraine", Dep of AMI, Kharkiv; I. Kovalskyy, Y. Zhukova, Nikolayev City Hospital #1, Nikolayev; I. Katerenchuk, L. M'yakinkova, HMEI of Ukraine "UMSA", Poltava Reg.Cariol. Hospital, Poltava; A. Parkhomenko, Y. Lutay, NSC "M.D. Strazhesko Institute of Cardiology" NAMS of Ukraine", Kyiv; V. Syvolap, S. Kyselov, Zaporizhzhya City Clin Hosp of Emergency Care, ZSMU, Zaporizhzhya; I. Vakaliuk, R. Nesterak, Ivano-Frankivs'k RC cardio Hospital.I-F SMU, dep of Int Dis, Ivano-Frankivs'k; V. Nikonov, O. Feskov, MI of HC "Kharkiv City ClinHospital of Emerg Care O.I.Meshchaninov".KhMAPE, Kharkiv; B. Goloborodko, Y. Golovtsev, Prof. L.Y. Aleynikova Odessa City Clinical Hospital #3, Odessa; I. Berezniakov, M. Lebedynska, MI of HC "Kharkiv City Clinical Hospital No 25" Dep. Of Terapy, KhMAPE, Kharkiv; L. Rudenko, I. Tutov, Kyiv City Emergency Care Hospital. MI Dep, Kyiv.

UNITED KINGDOM (319 patients, 16 centers)
National Lead Investigator: A. Brady
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Supplementary Methods

Inclusion Criteria:

1. Subject of any sex or race.
2. Subjects with planned PCIs as management for the qualifying ACS event were to undergo a PCI prior to randomization and within the 10-day period after the initial hospitalization for the event. Although subsequent staged PCI procedures were permitted in the study, all planned PCIs known at screening were to be completed within 30 days of randomization, and whenever possible, PCI procedures (including staged procedures) known to be indicated at the time of screening were to be completed prior to randomization.
3. Subject must have NSTE-ACS or STEMI according to the following criteria:
   a. A NSTE-ACS subject participating in the EARLY-ACS Study (Protocol No. P03684) who had been clinically stabilized (Section 7.3.2) was eligible for entry in the current study under Protocol No. P0103 within 10 days of presenting to the hospital. The subject must have completed the 96-hour primary endpoint of the acute segment of EARLY-ACS treatment (the acute segment of EARLY-ACS treatment was the initial phase of administration of randomized treatment with eptifibatide or matching placebo through catheterization) and was clinically stable before enrolling in the current study.

      -OR-

   b. Subjects not participating in the EARLY-ACS Study, but who were defined as NSTE-ACS (unstable angina or NSTEMI) by meeting all of the following criteria, and were clinically stable for at least 24 hours prior to screening/randomization, were eligible to enter directly into the current study ≤10 days (≤240 hours) of acute admittance into a hospital:
      1) The subject experienced symptoms of cardiac ischemia
      2) 50 years of age; and
      3) ANY 1 of the following criteria:
         a) Electrocardiogram changes by either of the following:
            [1] New or presumably new ST-segment depression ≥0.1 mV in at least 2 contiguous ECG leads; or
            [2] Transient (<30 minutes) ST-segment elevation ≥0.1 mV in at least 2 contiguous ECG leads.
         b) Any of the following cardiovascular biomarkers elevated >ULN:
            [3] Troponin I;
            [4] Troponin T; and/or
            [5] Creatine kinase-MB fraction (CK-MB).
         c) Diabetes mellitus;
         d) History of prior MI;
         e) History of peripheral arterial disease;
         f) History of cerebrovascular disease;
         g) History of CABG ≥3 years prior to entry (Note: This is 1 item in a list of 8 criteria. If the subject had CABG within the 3 years prior, they still may be eligible if at least one criterion of a–f or h from this list was met.);
         h) Multivessel coronary artery disease previously documented by catheterization (2 or 3 vessels with ≥50% stenosis) including the catheterization performed during the index admission for the qualifying event.

      Note: It was strongly recommended that each high-risk NSTE-ACS (unstable angina or NSTEMI) subject not enrolled in the EARLY-ACS study undergo a cardiac catheterization within 72 hours of acute presentation. All study sites must have had access to catheterization or other invasive procedures to ensure that all subjects are provided a similar standard of care.

-OR-

c. A subject who had been clinically stable for at least 24 hours following a high-risk STEMI as defined by the following criteria may have been enrolled in the current study within 10 days of acute admittance into a hospital:
    1) The subject has experienced symptoms of cardiac ischemia at rest with at least one episode lasting at least 30 minutes in conjunction with the clinical event prompting hospitalization; and
    2) The subject must have all three of the following:
        a) New or presumably new electrocardiogram (ECG) changes characterized by any of the following:
            [1] Persistent ST-segment elevation ≥0.1 mV in at least 2 contiguous ECG leads;
            [2] Pathologic Q waves in at least 2 contiguous ECG leads; or Left bundle branch block (LBBB).
        b) Any of the following biomarkers elevated >ULN:
            [1] Troponin I;
            [2] Troponin T; and/or
            [3] CK-MB.
        c) One of the following characteristics:
            [1] Presence of an acute anterior ST-elevation myocardial infarction; or
            [2] ≥50 years of age.

4) Subject met the following criteria for LDL-C concentrations at the time of admittance into a hospital (LDL-C was measured within the first 24 hours of admittance and met the following criteria):

a. Definitions of “chronic prescription lipid-lowering therapy” and “lipid-therapy naïve”:
    1) A subject was considered to be receiving chronic prescription lipid-lowering therapy if he/she had been receiving any prescription lipid-lowering therapy continuously for >4 weeks prior to and continuing until the qualifying ACS hospital admission.
    2) All other subjects (including those who initiate prescription lipid-lowering therapy after the qualifying ACS hospital admission) are considered to be ”lipid-therapy naïve.”
    3) To be eligible, a subject receiving chronic prescription lipid-lowering therapy must be receiving therapy with a lipid-lowering potency equal to or less than simvastatin 40 mg QD.
        a) A subject receiving chronic lipid-lowering therapy with LDL-C lowering potency greater than simvastatin 40 mg will not be eligible (Exclusion Criterion #5). The prohibited chronic lipid-lowering therapies are the following:
            [1] All doses of simvastatin >40 mg;
            [2] All doses of atorvastatin □40 mg;
            [3] All doses of rosuvastatin;
            [4] All doses of Ezetimibe/Simvastatin Combination; Ezetimibe coadministered with any dose of any statin.
        b) For the purposes of this protocol, all other chronic prescription lipid lowering therapies will be considered equal or less potent than simvastatin 40 mg QD and subjects taking such therapies may be considered for enrollment.
b. A lipid-therapy naïve subject was eligible if his/her LDL-C concentration was ≥50 mg/dL (≥1.3 mmol/L) and ≤125 mg/dL (≤3.2 mmol/L);
c. A subject receiving chronic prescription lipid-lowering therapy (received any lipid-lowering therapy continuously for >4 weeks prior to and continuing until the qualifying ACS hospital admission) was eligible to enroll, if his/her LDL-C concentration is ≥50 mg/dL (≤1.3 mmol/L) and ≤100 mg/dL (≤2.6 mmol/L).

d. The following conditions were observed concerning lipid concentrations and experience with chronic prescription lipid-lowering therapy:
    1) Blood lipid levels, including LDL-C, were measured as close as possible to each subject's presentation to a hospital, but not later than 24 hours after admission. A subject's baseline LDL-C and lipid-lowering therapy status were to be based on the subject's status at the time of the initial acute event leading to admittance into a hospital.
    2) The specimens did not need to be obtained after fasting. In addition if the blood lipid levels were not measured at the time of admittance, they could be be determined later on blood from the subject that was obtained at the time of admittance into the hospital.
    3) If a recent lipid panel (<6 months prior to presentation) was available, those values could be used for subject screening and determination of eligibility if the subject's therapy had not changed since the lipid measurement and if no specimen was drawn within the first 24 hours after admission to a hospital.
    4) If only a total cholesterol (TC) level was available at the time of admission, the subject was still eligible if TC concentrations met the following criteria at the time of admission and repeat lipid measurements (preferred but not obligate fasting) obtained as soon as possible (preferably within 24 hours of admission) met the above LDL-C criteria:
        a) TC concentration ≤190 mg/dL (≤4.9 mmol/L) for a lipid-therapy naïve subject;
        b) TC concentration ≤150 mg/dL (≤3.9 mmol/L) for a subject receiving chronic prescription lipid-lowering therapy.

5) Subjects must have had a plasma triglyceride (TG) level ≤350 mg/dL (≤4.0 mmol/L). A subject found to have a non-fasting TG >350 mg/dL (>4.0 mmol/L) upon admittance into a hospital, but had TG <1500 mg/dL (<17.0 mmol/L), had to have a TG ≤350 mg/dL (≤4.0 mmol/L) on a fasting specimen obtained as soon as possible (preferably within 24 hours of admission).
6) Subjects clinical laboratory tests had to be within reference ranges or clinically acceptable to the investigator/sponsor.
7) At screening/randomization, women of child-bearing potential must have agreed to use a medically accepted method of contraception while receiving protocol-specified medication and for 6 weeks after stopping the medication. All postmenarchal women who were <2 years menopausal or who had not had surgical sterilization or a hysterectomy were considered to be women of childbearing potential. Acceptable methods of contraception included condoms (male or female) with or without a spermicidal agent, diaphragm or cervical cap with spermicide, medically prescribed intrauterine device (IUD), oral or injectable hormonal contraceptive, and surgical sterilization (eg, hysterectomy or tubal ligation).
8) Each woman of child-bearing potential who was not currently sexually active must have agreed to use a medically accepted method of contraception should she become sexually active while participating in the study.

Exclusion Criteria:

A subject was excluded from entry if any of the criteria listed below were met:

1. Subject was clinically unstable. A subject was considered clinically unstable if he/she displayed any of the following events within 24 hours prior to Screening/Randomization:
    a. Hemodynamic events:
        1) Hypotension, defined as sustained systolic blood pressure of <90 mmHg due to cardiac failure with associated symptoms;
        2) Unstable or severe Pulmonary edema/decompensated CHF;

3) Acute mitral regurgitation;
4) Acute ventricular septal defect.

b. Recurrent symptoms of cardiac ischemia:
c. Stroke or transient ischemic attack (TIA);
d. Arrhythmic events:
    1) Ventricular fibrillation;
    2) Sustained ventricular tachycardia lasting >30 seconds or in association with symptoms;
    3) Complete heart block;
    4) High grade second degree heart block

2. Subjects who planned or underwent CABG in response to the initial episode of ACS.
3. Subjects who needed to continue the following concomitant medications: cyclosporine, diltiazem, danazol, amiodarone, verapamil, niacin, fibrates as concomitant medications or any of the potent CYP3A4 inhibitors, itraconazole, ketoconazole, erythromycin, clarithromycin, and telithromycin, HIV protease inhibitors, nefazodone, probucol, resins, grapefruit juice >1 quart/day, torceptrapib, and any investigational drugs. Routes of administration other than oral or parenteral (eg, topical, intraocular, otic) of antifungal or antibiotics were acceptable. Short-term therapy of any prohibited medication was acceptable, provided study medication was interrupted during the administration and restarted after short-term therapy was completed.
4. The investigator felt that discontinuation of existing lipid-lowering regimen posed a risk to the subject.
5. The subject who was receiving chronic prescription lipid-lowering therapy with LDL-C lowering potency greater than simvastatin 40 mg. Note: If potent prescription lipid-lowering therapy was begun after hospitalization and was not administered chronically prior to hospitalization, then the subject was not to be excluded.
    a. Chronic lipid-lowering therapy with LDL-C potency greater than simvastatin 40 mg were:
        1) All doses of simvastatin >40 mg;
        2) All doses of atorvastatin ≥40 mg;
        3) All doses of rosuvastatin;
        4) All doses of Ezetimibe/Simvastatin Combination;
        5) Ezetimibe coadministered with any dose of any statin.
    b. For the purposes of this protocol, all other chronic prescription lipid-lowering therapies were to be considered equal or less potent than simvastatin 40 mg QD and subjects taking such therapies could be considered for enrollment.
6. Subject had an allergy/sensitivity to any statin, ezetimibe, and/or their excipients.
7. Subject had active liver disease or persistent serum transaminase elevations (≥2 x ULN). Subjects with transient increases in serum transaminases due to the index MI could be enrolled.
8. Subjects with calculated creatinine clearance (CrCl) <30 mL/min or dialysis within 30 days. Creatinine clearance was calculated according to the Cockcroft-Gault equation.
9. Subject who had a history of alcohol and/or drug abuse.
10. Subject was a pregnant or lactating woman, or woman intending to become pregnant. Note: Each female subject of child-bearing potential must have had a serum or urine pregnancy test performed by the local laboratory at Screening/Randomization and the results of the pregnancy test must be negative (not pregnant) prior to randomization.
11. Subject with any clinically significant condition or situation, other than the condition being studied that, in the opinion of the investigator, would interfere with the study evaluations or optimal participation in the study
12. Subject who has used any investigational drugs within 30 days of screening/randomization.

13. Subject who was participating in any other clinical study involving an investigational drug or device with the following exceptions:
    a. A subject participating in the EARLY-ACS Study (Protocol No. P03684) was not necessarily excluded.
    b. A subject participating in clinical research of approved therapy being administered according to the therapy's labeled use was not to be excluded.
14. Subject with prior enrollment in this current study (Protocol No. P04103).
15. Subject who was part of the staff personnel directly involved with this study.
16. Subject who was a family member of the investigational study staff.

Listing of Study Endpoints

Primary Endpoint
The primary efficacy endpoint was the time from randomization until the first occurrence of any event in the composite endpoint:

- CV death
- Major coronary events
    - non-fatal myocardial infarction [MI]
    - documented unstable angina that requires admission into a hospital
    - all coronary revascularization with either PCI or CABG occurring at least 30 days after randomization)
- Non-fatal stroke

Secondary Endpoints
The secondary efficacy endpoints included time from randomization until the first occurrence of:

- Composite incidences of death due to any cause, major coronary events, or non-fatal stroke.
- Composite endpoint of CHD death, non-fatal MI, or urgent coronary revascularization with either PCI or CABG occurring at least 30 days after randomization.
- Composite endpoint of CV death, non-fatal MI, documented unstable angina that requires admission into a hospital, all revascularization (coronary revascularization and non-coronary revascularization) occurring at least 30 days after randomization, and non-fatal stroke.

Tertiary endpoints:

1. **Individual Endpoints**

Time from randomization until the first occurrence of each of the following individual events:

- Death from any cause
- CHD death
- CV death
- MI (fatal or non-fatal)
- Documented unstable angina that requires admission into a hospital
- All coronary revascularization with either PCI or CABG occurring at least 30 days after randomization
- Urgent coronary revascularization with either PCI or CABG occurring at least 30 days after randomization
- All revascularization (including both coronary and non-coronary) occurring at least 30 days after randomization
- Stroke (fatal or non-fatal)
- Any cardiovascular event leading to admission into a hospital, CHF that requires hospitalization occurring at least 30 days after randomization.

2. Proportion of subjects achieving reductions in LDL-C and hs-CRP:

- The LDL-C/hs-CRP endpoint is the percentage of subjects achieving concentrations of LDL-C <70 mg/dL (<1.8 mmol/L) in addition to hs-CRP <2.0 mg/L following 1 month and 4 months of treatment with Ezetimibe/Simvastatin Combination or simvastatin

Safety Measurements:
Clinical evaluations included the evaluation of routine adverse events, vital signs and relevant laboratory measurements. Events of special interest that were evaluated included consecutive elevations of AST and/or ALT to ≥3 ULN, incidence of myopathy, incidence of cholecystectomies, and incidence of all gallbladder-related adverse events.

Endpoint Definitions Used by the Independent Clinical Endpoint Committee

Death Classification

All deaths were reviewed and classified in 2 primary categories, Cardiovascular (CV) or non-CV deaths, and also in 2 secondary categories, coronary heart disease (CHD) death and non-CHD death. All deaths will be assumed Cardiovascular
(Category I below) in nature unless a Non-Cardiovascular (Category II) cause can be clearly shown, with the exception of death without any additional information, which will be classified as Unknown (Category III).
In secondary analyses, all-cause mortality and CHD death were analyzed. All-cause mortality included all deaths, regardless of whether the cause of death was determined. CHD death was defined as death due to atherosclerotic coronary heart disease, and included deaths due to acute MI, sudden death, non-sudden death, unwitnessed death, and procedure-related deaths (Category IA below). Non-CHD death includes deaths due to all other causes (Categories IB, IC, II, and III below).

Death was classified in the following categories:

I. Cardiovascular (CV) Death
   A. Atherosclerotic Coronary Heart Disease (=CHD Death)
      1. Acute Myocardial Infarction (MI):
         Fatal myocardial infarction was adjudicated in any one of the following three scenarios:
         a) Death occurring after a documented myocardial infarction in which there was no conclusive evidence of another cause of death. Subjects who were being treated for MI and who had a sudden death, as the terminal event related to the MI were classified as having a MI-related death.
         b) Autopsy evidence of a recent infarct with no other conclusive evidence of another cause of death.
         c) A Fatal Myocardial Infarction could be adjudicated for an abrupt death that had suggestive criteria for an infarct but did not meet the strict definition of a MI infarction. The suggestive criteria were as follows:
            1) Presentation of chest pain; AND one of the following:
               (a) ECG changes indicative of a myocardial injury; or
               (b) Abnormal markers without evolutional changes (i.e. subject died before a subsequent draw); or
               (c) other evidence of new wall motion abnormality.
      2. Sudden Death:
         Defined as death that occurred suddenly and unexpectedly in which the time of death was known. Death must have been documented to have occurred within 24 hours of last being known alive. For example, a subject who had had increasing angina for the previous five days prior to death and had been seen to be in his usual state by his wife at bed time, but is found dead the next morning 10 hours later, would be classified as a sudden death due to atherosclerotic heart disease. The same classification would apply if the death occurred without preceding change in cardiovascular symptoms.
      3. Non-Sudden Death:
         This category referred to a subject who had had symptoms of a cardiovascular nature and has had gradual deterioration prior to death. For example, a subject admitted with worsened heart failure who, despite therapy, gradually deteriorated and ultimately died. This would have implied a deterioration in a subject who may have started off at New York Class I or II but deteriorated over time. It could also

have applied to a class III or IV subject who also deteriorated with time.

4. Unwitnessed Death (not seen >24 hrs):
   Death that occurred unexpectedly and had no known other major causes of death. To be classified as an unwitnessed death, the subject must also have been last known to be alive >24 hours.
5. Procedural:
   Related to any of the usual coronary artery procedures such as surgery, PCI, or angiography. This applied to any or all complications occurring during the same hospitalization, or within seven days of the event.

B. Atherosclerotic Vascular Disease, Excluding Coronary Disease.
   Atherosclerotic vascular disease excluded coronary artery disease. These atherosclerotic vascular disease categories were straight forward, but as much detail was to be provided as possible. With respect to aortic mesenteric, renal vascular, peripheral vascular disease or other, as much detail was to be provided as possible about the nature of the condition, the time-course and the event causing death. If possible, one was to try to describe whether coronary or cerebrovascular disease also contributed to the fatal demise.
   1. Cerebrovascular Disease:
      Cerebrovascular disease also included stroke, hemorrhage, and cerebrovascular peri-procedural deaths.
   2. Other:
      Other included non-cerebral, non-coronary vascular causes of death (eg, aortic, mesenteric, renal vascular, and peripheral vascular disease) or procedures related to these vascular beds (eg, AAA repair) when the circumstances surrounding the death could be linked to a vascular procedure.

C. Other Cardiovascular Disease (Non-Atherosclerotic)
   In all of these conditions, one should have provided as much detail as possible in the narrative, and specify whether in the investigator's opinion, atherosclerotic disease played a part and if so, how. Examples include death due to pulmonary embolism, endocarditis, valvular heart disease, cardiac valve surgery.

II. Non-CV Death
   Non-CV Death comprised straightforward categories and needed no description, but as much detail as possible was to be provided. The extent to which atherosclerotic disease played a part was to be addressed.
   1. Accidental;
   2. Diabetes;
   3. Malignancy;
   4. Renal;
   5. Suicide;
   6. Other: The cause of death must be specified.

III. Unknown
   All other death was classified as unknown.

Non-Fatal Endpoint Definitions

The following non-fatal endpoints were reviewed by the CEC:

1. Myocardial Infarction
   All definite myocardial infarctions were counted as events whether they represented the reason for the hospitalization or occurred during a hospitalization. In addition, they were

counted as events whether they occurred spontaneously or as the direct consequences of an investigation/procedure or operation. The definition of MI as an endpoint was taken into account whether a subject had a recent MI or had undergone revascularization with PCI or CABG surgery. In order to meet the criteria as an endpoint, an MI must have been distinct from the qualifying event (i.e., re-infarction for a subject who qualified for the study based on recent MI). An MI was considered to be present at the initial presentation of the qualifying ACS event if at presentation or ≤8 hours, troponin I or T, or CK-MB was elevated >1X ULN. If troponin I or T, or CK-MB was elevated <16 hours from presentation, and no symptoms, PCI, or CABG had occurred in the first 16 hours after presentation and enrollment, this also was considered an MI at presentation. Two definitions of myocardial infarction were evaluated by the CEC during adjudication of suspected cases of MI –the IMPROVE-IT MI definition and the EARLY ACS MI definition -- as described below. The primary analysis utilized the IMPROVE-IT MI definition.

a. IMPROVE-IT MI Definition (Table 1):
    1) Myocardial infarction was defined by a clinical scenario consistent with MI, confirmed by the presence of either ECG evidence or cardiac marker evidence (post-CABG, both ECG and cardiac marker evidence were required, if the CK-MB was ≥5X ULN to <10X ULN).
        a) ECG evidence of infarction or re-infarction required new Q-waves (≥0.04s) in two or more contiguous leads that was not an ambiguous change from baseline.
        b) Cardiac marker evidence of infarction (or reinfarction) required troponin or CK-MB elevation greater than the ULN, or when neither troponin nor CK-MB were available, elevation of the total CK ≥2X ULN. Following PCI, CK-MB (or CK) elevation had to be ≥3X ULN. Following CABG, CK-MB (or CK) elevation had to be ≥5X ULN (if accompanied by ECG criteria) or ≥10X ULN (without ECG criteria). The reviewers should also consider the clinical features (eg, renal insufficiency), possible alternative diagnoses (eg, pericarditis), pattern of marker release (eg, absence of a rise and fall), and known sensitivity/specificity of the various cardiac markers in the adjudication of infarction, particularly when there is discordance in the results of multiple markers.
    2) Additional requirements for an endpoint MI, applicable to particular cases, were as follows:
        a) In subjects with acute MI as the index event, within the first 72 hours after the index MI, enzyme criteria for recurrent infarction were re-elevation of the troponin or CK-MB >ULN and increased by at least 50% over the previous value. If neither the troponin nor CK-MB were available, total CK must have been ≥2 x ULN and increased by at least 50% over the previous value. Following PCI, CK-MB (or CK) elevation must have been ≥3 x ULN and increased by at least 50% over the previous value.
        b) In the 72-hour period following CABG, the definition for a recurrent infarction required both enzyme and ECG criteria if the CK-MB (or total CK if CK-MB was not available) was ≥5X ULN but <10X ULN. If the cardiac markers were ≥10X ULN, ECG criteria were not required. The CEC could have also considered information regarding new wall motion abnormalities (when available) in determining whether an MI occurred post-CABG.

b. Defined in the EARLY-ACS Trial:
    1) No MI at Presentation, no Recent Revascularization.
    In subjects who did not have an MI at presentation and have not had a recent (<24 hours) revascularization, an endpoint MI was defined by cardiac markers of necrosis or ECG evidence: elevation of CK-MB ≥2X ULN, troponin (I or T) ≥2X ULN, total CK ≥2X ULN (if no CK-MB values were available), or new, significant (≥0.04 s) Q-waves

in ≥2 contiguous leads.

2) Presentation MI Present, no Recent Revascularization.
   In subjects who had an MI at presentation, who had not had a recent revascularization, an endpoint MI was defined by cardiac markers of necrosis or ECG evidence as follows: re-elevation of CK-MB to ≥2 x ULN (if prior level was normal), CKMB ≥2X ULN and ≥50% above the prior level (if prior level was above normal), total CK ≥2X ULN and increased by ≥50% over the previous value (if CK-MB was unavailable), or new, significant (≥0.04 s) Q-waves in ≥2 contiguous leads and discrete from enrollment MI. In the absence of CK-MB and total CK data, the CEC could have considered troponin data, in which case the troponin must exceed ≥2X ULN and be ≥50% above the prior level if the prior level was ≥ULN.

3) No Recent MI Prior to the Current Revascularization.
   For subjects who have not had a recent MI or if preprocedure cardiac markers were ≥ULN and who have had revascularization, an endpoint MI was defined as follows:
   a) Peri-PCI: CK-MB (or total CK, if CK-MB is unavailable) ≥3 x ULN. In the absence of CK-MB and total CK data, the CEC could have considered troponin data, in which case the troponin value must have exceeded ≥3X ULN.
   b) Peri-CABG: CK-MB (or total CK, if CK-MB is unavailable) ≥5X ULN.
   c) Any revascularization: New, significant (≥0.04 s) Q-waves in 2 contiguous ECG leads.

4) Revascularization in the Setting of Pre-Procedure MI
   In subjects in whom the cardiac markers of necrosis were elevated prior to a revascularization, an endpoint MI was defined as follows:
   a) Peri-PCI: CK-MB (or total CK, if CK-MB was unavailable) ≥3 x ULN and increased by ≥50% from the level before the procedure.
   b) Peri-CABG: CK-MB (or total CK, if CK-MB was unavailable) ≥5 x ULN and increased by ≥50% from level before the procedure.
   c) Any revascularization: New, significant (≥0.04 s) Q waves in 2 contiguous ECG leads that were present on the post-procedure ECG but not present on the pre-procedure ECG.

Note: Cardiac troponins (I or T) often are used to diagnose MI and are part of the MI definition proposed by an ESC/ACC Consensus Statement. Because troponin values may remain elevated for 7–10 days or longer after an index MI, the relationship of degree of incremental troponin elevation with endpoint reinfarction and outcome is unknown, and the bimodal pattern of troponin T release creates difficulty in specifying a true “re-elevation”, the use of troponin to define an EARLY ACS endpoint MI definition has limitations, particularly for defining reinfarction within this 7–10 day window. For these reasons, the EARLY ACS protocol mandated CK and CK-MB collection in subjects with suspected infarction and after PCI and CABG, but there may have been subjects who had a suspected infarction without available CK/CK-MB but in whom troponin data were available. For these subjects, an EARLY ACS MI could have been adjudicated by the CEC to have occurred when there was a preponderance of clinical evidence based on signs, symptoms, ECG changes, and troponin data.

Table 1 Recurrent Acute Coronary Syndrome: IMPROVE-IT MI and Documented Unstable Angina Requiring Admission Into a Hospital

	Clinical Presentation	ECG Criteria	Cardiac Markers: Troponin, CK-MB (Preferred if Post Revascularization), CK[a]
MI [b] No recent MI (<72 hr) or recent revasc (<24 hr)	• Investigator must have a clinical suspicion of MI, AND ➔	• Requires new Q-waves (≥0.04 s) in 2 or more leads OR ➔	Troponin >ULN (If Troponin results are given in ranges, ULN is the lowest value in the "indicative of necrosis" range) Or CK-MB >ULN Or CK ≥2 x ULN (If neither CK-MB nor troponin are available)
MI: Within 24 hr Post PCI (no prior MI <72h)	N/A	• Requires new Q-waves (≥0.04s) in 2 or more leads OR ➔	CK-MB ≥3x ULN Or CK ≥3 x ULN (If CK-MB not available) Or Troponin ≥3 x ULN (If neither CK-MB nor total CK available)
MI: Within 72 hr Post CABG (no prior MI <72h) [c]	N/A	• Requires new Q-waves (≥0.04 s) in 2 or more leads AND ➔ OR • Absence of new Q-waves (≥0.04s) in 2 or more leads AND ➔	CK-MB ≥5 x ULN Or CK ≥5 x ULN (If MB not available) CK-MB ≥10 x ULN Or CK ≥10 x ULN (If MB not available)
MI: Within 72 hr of a prior MI	• Investigator must have a clinical suspicion of MI AND ➔	• Requires new Q-waves (≥0.04 s) in 2 or more leads OR ➔	Troponin >ULN Or CK-MB >ULN Or CK ≥2 x ULN (If neither CK-MB nor troponin are available) N.B. If prior level elevated then values must also be ↑ at least 50% over previous value
MI: Within 72 hr of MI: Post PCI	N/A	• Requires new Q-waves (≥0.04 s) in 2 or more leads OR ➔	CK-MB ≥3x ULN Or CK ≥3 x ULN (If MB not available) Or Troponin ≥3 x ULN (If neither CK-MB nor total CK available) N.B. If prior level ↑ then value must also be ↑ ≥50% over previous value

2. Documented Unstable Angina Requiring Admission into a Hospital
   In order to meet the criteria as an endpoint, the subject must first have had an episode of ischemic discomfort consistent with unstable angina (ischemic discomfort either at rest, of new onset, or in an accelerating pattern) lasting ≥10 minutes, which occurred before the subject presented to the hospital. The subject must then have been hospitalized (including a stay in the emergency department or observation unit of at least 12 hours) and have had at least one of the following to meet the criteria for unstable angina requiring rehospitalization:
   a. Another episode of ischemic discomfort that occurred after arrival to the hospital and occurred at rest, lasting ≥10 minutes, was distinct from the episode that occurred outside of the hospital, and that was attributed to myocardial ischemia according to the treating physician.
      -OR-

b. New ST segment or new T-wave changes consistent with ischemia in two or more contiguous leads in association with an episode of ischemic discomfort. Note: If subjects were admitted with suspected unstable angina, and subsequent testing revealed a non-cardiac or non-ischemic etiology, this would not be recorded as meeting this primary endpoint (or composite thereof).

3. Stroke

Stroke was defined as an acute new neurological deficit ending in death or lasting >24 hours, and classified by a physician as a stroke. Stroke was subclassified into one of the following 4 groups:

a. Primary Hemorrhagic: an intracerebral hemorrhage or subdural hematoma:
   1) Intracerebral Hemorrhage: Stroke with focal collections of intracerebral blood seen on a brain image (CT or MRI) or a postmortem examination, not felt to represent hemorrhagic conversion. Subarachnoid hemorrhage was included in this category.
   2) Subdural Hematoma: density fluid collection in subdural space on brain images or blood in the subdural space on autopsy.
b. Nonhemorrhagic Cerebral Infarction: Stroke without focal collections of intracerebral blood on a brain image.
c. Nonhemorrhagic Infarction with Hemorrhagic Conversion: Cerebral infarction with blood felt to represent hemorrhagic conversion and not a primary hemorrhage.
d. Uncertain: Any stroke without brain imaging (eg, CT or MRI), surgical exploration, autopsy, other documentation of type, or if tests are inconclusive.

4. Coronary Revascularization

This endpoint was investigator-determined based on information reported on the CRF and did not require CEC review or adjudication. Coronary revascularization occurring at least 30 days post randomization was defined as all PCI and CABG performed >30 days (i.e., after 30 24-hour periods had passed) after randomization was counted as an endpoint event. Attempted revascularization procedures, even if not successful, were counted. Revascularization was divided by type and urgency. Urgent Revascularization was defined as coronary revascularization (PCI or CABG) that occurred during a hospitalization prompted by myocardial infarction or recurrent unstable angina with an episode of ischemic discomfort at rest lasting at least 10 minutes.

Definitions of Unexplained Myalgia, Myopathy and Rhabdomyolysis

To satisfy the IMPROVE-IT definition of unexplained myalgia, myopathy or rhabdomyolysis, the subject must have had symptoms of myalgias (muscle aches, weakness, or tenderness) without an obvious cause such as skeletal muscle trauma or recent heavy exercise.

1. Unexplained Myalgia

Unexplained myalgia was defined as new muscle pain, tenderness, or weakness without another obvious cause (eg, recent heavy exercise, fall). Unexplained myalgia was further subclassified as either associated with an elevation in the total CK above the upper limit of normal or not associated with a CK elevation (i.e., CK <ULN). NOTE: There should have been no other cause of an elevated CK (eg, recent MI).

2. Myopathy

Myopathy was defined as new muscle pain, tenderness, or weakness without another obvious cause (i.e., myalgia) that was associated with an elevation of total CK that satisfied either of the following two criteria:

a. Total CK ≥10X upper limit of normal on one occasion;
b. Total CK ≥5X upper limit of normal on two consecutive readings.

NOTE: There should be no other cause of an elevated CK (eg, recent MI).

3. Rhabdomyolysis

Rhabdomyolysis was defined as an episode of new muscle pain, tenderness, or weakness without another obvious cause (i.e., mylagia) with either marked total CK elevation without renal dysfunction (a), or
an episode of myopathy with evidence of clinically significant renal dysfunction (b):

a. Rhabdomyolysis Without Renal Dysfunction (must satisfy both criteria):
    1) New muscle pain, tenderness, or weakness without another obvious cause (i.e., unexplained myalgia);
    2) Total CK elevation ≥10,000 IU/L. *NOTE: There should be no other cause of an elevated CK (eg, recent MI).*
b. Rhabdomyolysis With Renal Dysfunction (must satisfy all 3 criteria):
    1) New muscle pain, tenderness, or weakness without another obvious cause (i.e., unexplained myalgia);
    2) Total CK elevation either ≥10X ULN on one occasion or ≥5 X ULN, but <10X ULN on two consecutive occasions. NOTE: There should be no other cause of an elevated CK (eg, recent MI).
    3) Associated with evidence of clinically significant renal dysfunction defined as satisifying at least one of the following:
        a) Creatinine elevation that is either ≥0.5 mg/dL absolute or ≥50% relative to the baseline creatinine;
        b) Associated with myoglobinuria or dark urine.

CLASSIFICATION OF MALIGNANCIES

All reported malignancies that were diagnosed after randomization or that were present prior to randomization and then worsened or recurred after randomization were reviewed and classified as follows using pathology data as the primary source of classification. If a pathology report was not available to establish the presence of a malignancy, the CEC could use the total of the available clinical evidence and the following definitions to classify the events as either a malignant tumor, benign tumor, or not a tumor.

- Malignant tumor - an abnormal mass of tissue that can invade and destroy nearby tissue, and that may spread (metastasize) to other parts of the body.
- Benign tumors – an abnormal mass of tissue that can not invade/destroy nearby tissue or metastasize.
- Not a tumor – neither of the above.

The date of the initial clinical appearance (date of the first sign, symptom, or clinical test that identified the presence of a tumor) of the tumor was recorded by the CEC. For tumors that were present prior to randomization, the CEC determined whether the tumor relapsed (i.e., was considered cured prior to randomization, but then after randomization the same tumor recurred), progressed (tumor was in remission or controlled prior to randomization, then after randomization advanced in size/location/stage), or neither relapsed nor progressed (i.e., the tumor remained clinically stable after randomization in terms of stage/location/size). The CEC also reported the location, extent, and relationship to vital status of all tumors (malignant and benign).

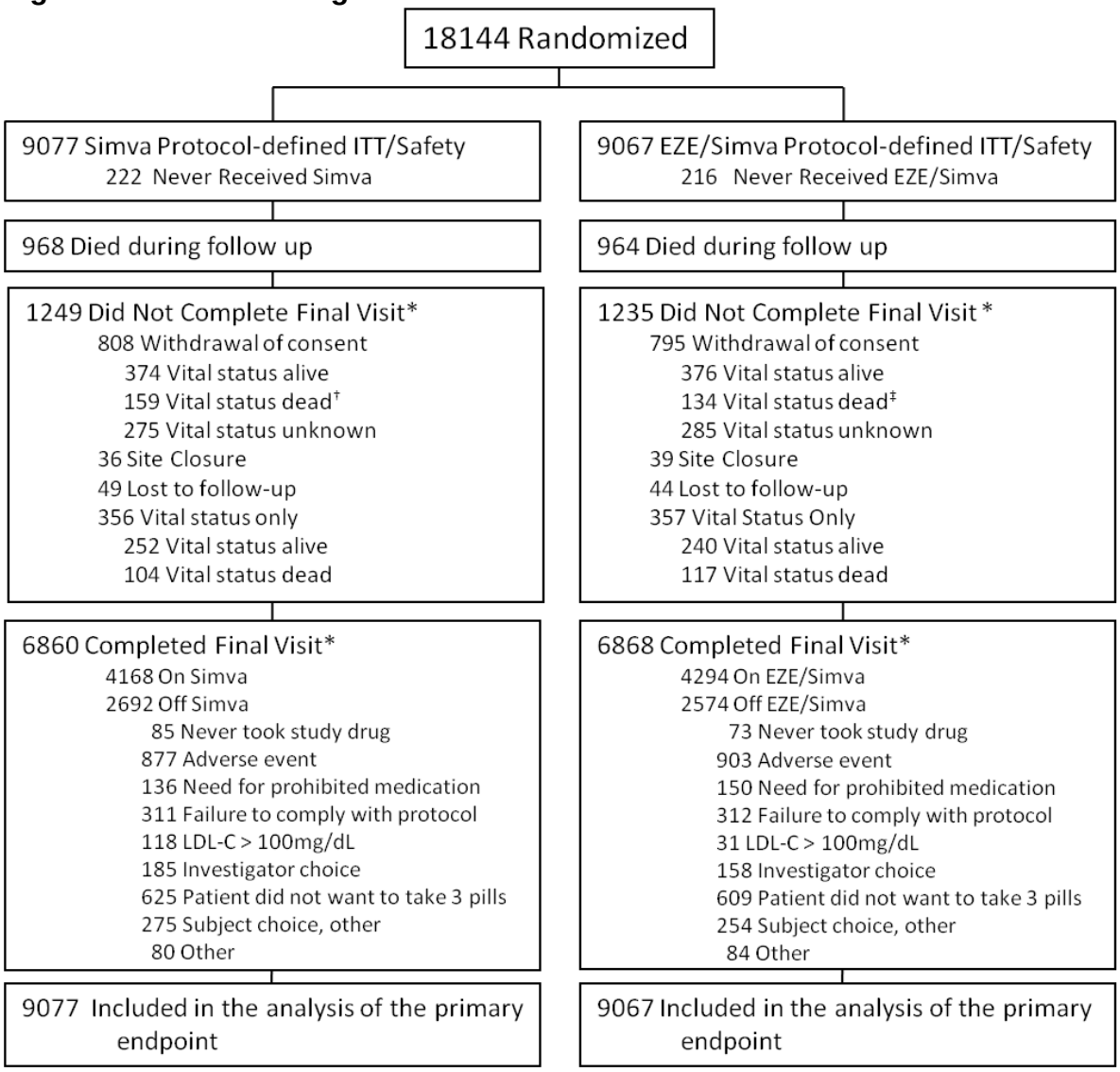
Reconciliation of non-cardiovascular hospitalization information

Shortly before the primary IMPROVE-IT data base lock, it was discovered that some non-cardiovascular hospitalizations were not reported as serious adverse events (note that hospitalizations >24 hours were to be categorized as SAEs, whatever the reason for hospitalization). Based on the fact that these additional events were highly unlikely to affect the primary and key secondary efficacy and safety endpoints, a primary database lock was conducted to support the AHA presentation and publication.

During the pre-specified reconciliation process of this hospitalization information, a small number of efficacy and malignancy endpoints were identified and confirmed at adjudication. There were 2 primary endpoints identified, 1 hemorrhagic stroke in the simvastatin/placebo group and 1 ischemic stroke in the simvastatin/ezetimibe group. In addition, there was 1 subsequent endpoint in the simvastatin group – an unstable angina hospitalization that occurred after another component of the primary endpoint had already occurred. There were also 3 cancers identified, (2 in the ezetimibe/simvastatin group, where one was a first occurrence of cancer and 1 was a subsequent cancer whose diagnosis was made 13 days after another cancer diagnosis) and 1cancer in the simvastatin/placebo group, which pre-dated another cancer diagnosis by one day. As pre-specified, these endpoint events are not included in the primary analysis result, and would not substantively change the primary or secondary results.

Supplementary Figures

Figure S1: Consort Diagram



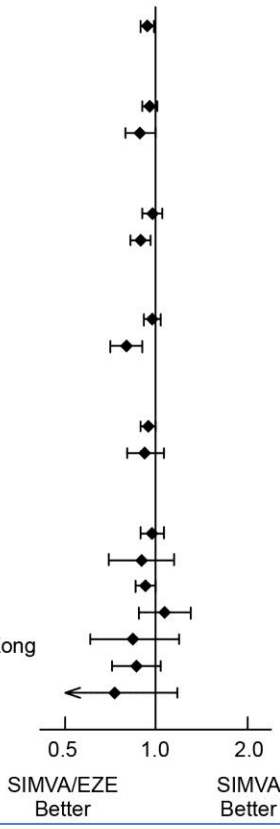
*Final visits occurred on or after May 1, 2014; Vital status recorded in 2014.
†Includes 28 CV deaths, 16 non-CV deaths during follow up and 115 deaths > 4 months after last contact (30 non-CV death, 85 unknown deaths); ‡Includes 14 CV deaths, 14 non-CV deaths during follow up and 106 deaths > 4 months after last contact (27 non-CV death, 79 unknown deaths)

The final study disposition of all study participants is summarized in Figure S1. Vital status after January 1, 2014 was obtained in 96.0% of all randomized participants. At study conclusion, there were 93 participants who were lost to follow-up and 75 participants from closed sites without known vital status. Vital status was identified for 713 participants who were lost prior to the close out period. During the study, 1603 subjects withdrew consent (1.6%/year) where vital status was obtained in 1043 subjects, including 42 subjects experiencing a cardiovascular death. The number of subjects categorized as site closure, lost to follow-up and withdrawn of consent was similar between randomized treatment groups.
Assessment of percent of potential follow-up for the primary endpoint and all-cause mortality:
For the primary endpoint subject-years of follow-up was based on the day of randomization to the day of the first occurrence of a primary endpoint event or the last office or phone visit, or day of death during follow-up; potential subject-years of follow-up was based on the day of randomization to the day of the

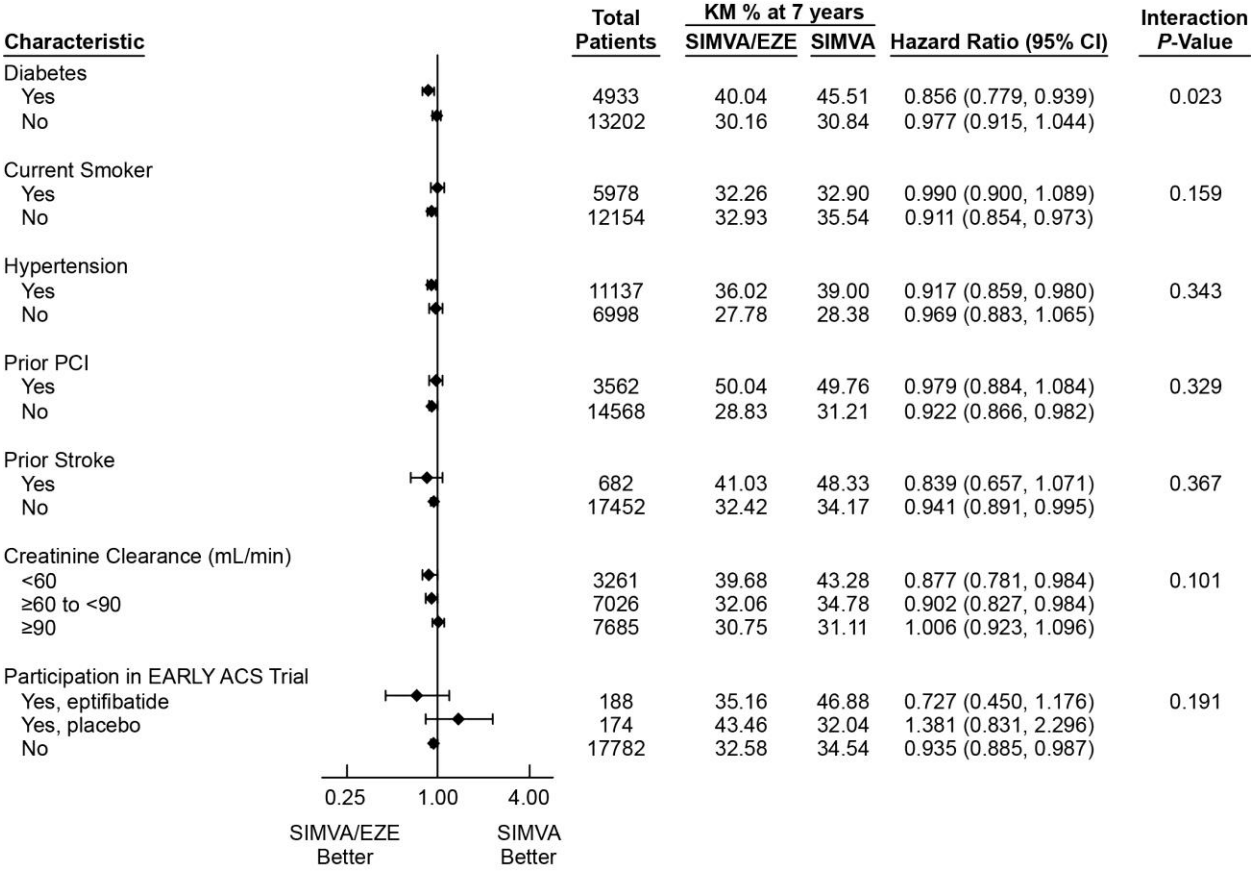
first occurrence of a primary endpoint event or the end of study, which was 5/1/2014 or the last visit on or after 5/1/2014, or the day of death. For all-cause mortality subject-years of follow-up was based on the day of randomization to the last known alive day or day of death; potential subject-years of follow-up was based on the day of randomization to the end of study, or the day of death. Percent of potential follow-up equals (subject-years of follow-up / potential subject-years of follow-up) x 100.

Figure S2: Primary Endpoint in Pre-specified Subgroups
A. Overall Study Population, Gender, Age, Race, and Region

Characteristic	Total Patients	KM % at 7 years SIMVA/EZE	KM % at 7 years SIMVA	Hazard Ratio (95% CI)	Interaction *P*-Value
Overall	5314	32.73	34.67	0.936 (0.887, 0.988)	
Gender					
Male	13728	33.26	34.87	0.952 (0.895, 1.012)	0.267
Female	4416	31.01	34.02	0.885 (0.791, 0.991)	
Age Group 1 (years)					
<65	10173	29.94	30.79	0.975 (0.904, 1.051)	0.098
≥65	7971	36.35	39.94	0.890 (0.824, 0.961)	
Age Group 2 (years)					
<75	15346	31.67	32.46	0.971 (0.915, 1.031)	0.005
≥75	2798	38.95	47.60	0.797 (0.704, 0.902)	
Race					
Caucasian	15202	33.06	35.02	0.939 (0.885, 0.995)	0.790
Non-Caucasian	2923	31.15	32.90	0.919 (0.799, 1.058)	
Region					
United States	5866	34.41	35.41	0.969 (0.883, 1.064)	0.575
Canada	1107	22.15	25.54	0.894 (0.698, 1.145)	
Western Europe	7274	33.92	35.87	0.923 (0.849, 1.002)	
Eastern Europe	1416	33.43	32.94	1.071 (0.878, 1.307)	
Malaysia/Singapore/Hong Kong	616	25.90	28.29	0.845 (0.602, 1.187)	
South America	1585	32.05	37.68	0.859 (0.714, 1.034)	
Australia/New Zealand	280	24.06	32.12	0.734 (0.460, 1.170)	



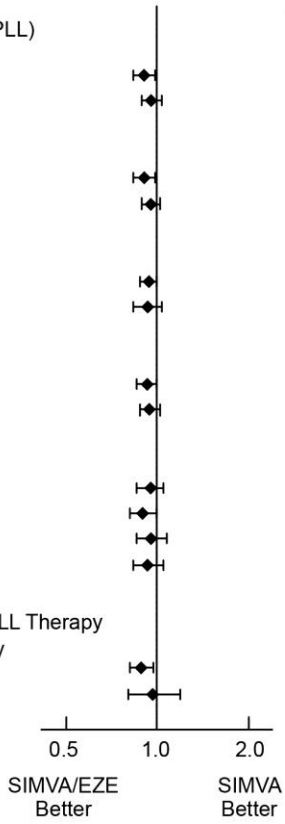
B. Diabetes, Smoking and Hypertension Status, Prior PCI and Stroke, Creatinine Clearance, High-risk ACS diagnosis, and Participation in EARLY ACS Trial



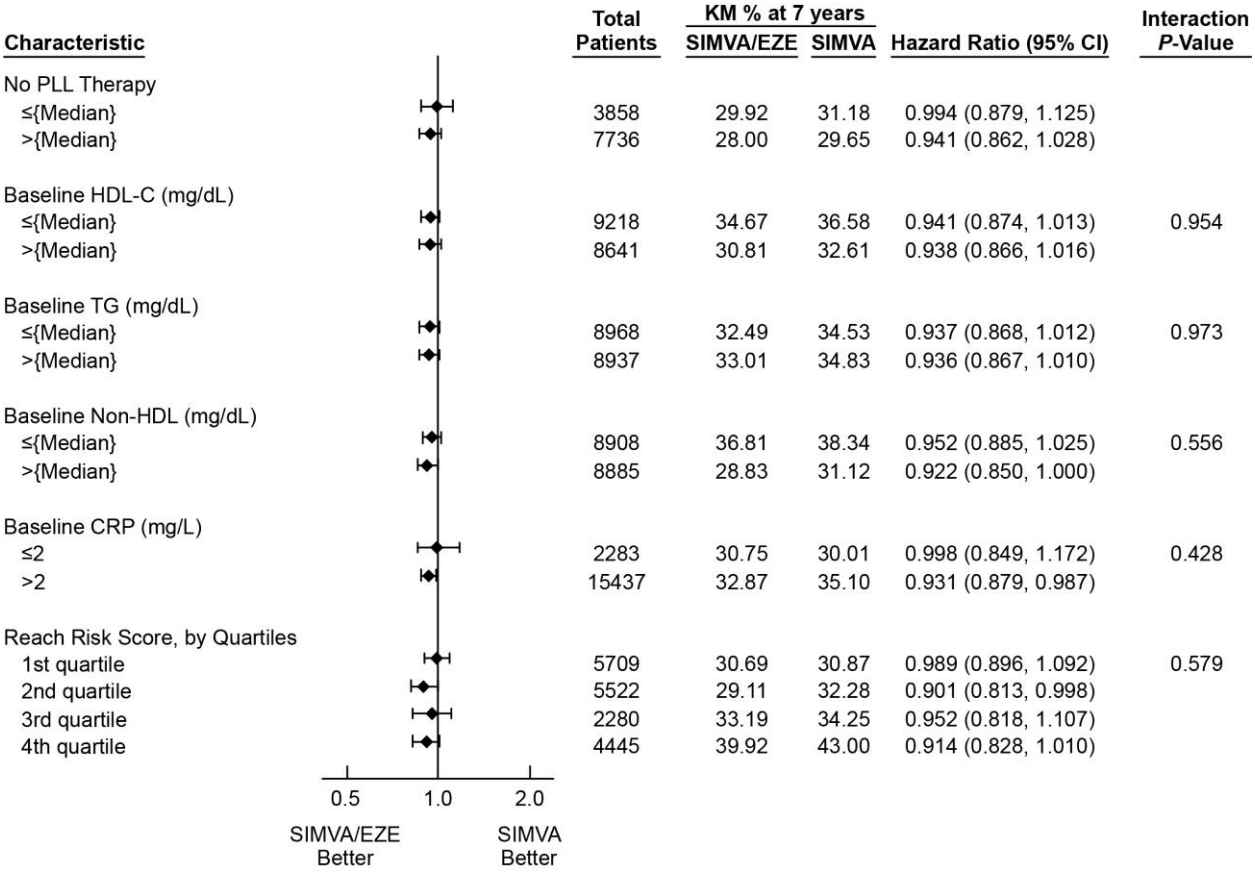
Characteristic	Total Patients	KM % at 7 years SIMVA/EZE	KM % at 7 years SIMVA	Hazard Ratio (95% CI)	Interaction *P*-Value
Diabetes					
Yes	4933	40.04	45.51	0.856 (0.779, 0.939)	0.023
No	13202	30.16	30.84	0.977 (0.915, 1.044)	
Current Smoker					
Yes	5978	32.26	32.90	0.990 (0.900, 1.089)	0.159
No	12154	32.93	35.54	0.911 (0.854, 0.973)	
Hypertension					
Yes	11137	36.02	39.00	0.917 (0.859, 0.980)	0.343
No	6998	27.78	28.38	0.969 (0.883, 1.065)	
Prior PCI					
Yes	3562	50.04	49.76	0.979 (0.884, 1.084)	0.329
No	14568	28.83	31.21	0.922 (0.866, 0.982)	
Prior Stroke					
Yes	682	41.03	48.33	0.839 (0.657, 1.071)	0.367
No	17452	32.42	34.17	0.941 (0.891, 0.995)	
Creatinine Clearance (mL/min)					
<60	3261	39.68	43.28	0.877 (0.781, 0.984)	0.101
≥60 to <90	7026	32.06	34.78	0.902 (0.827, 0.984)	
≥90	7685	30.75	31.11	1.006 (0.923, 1.096)	
Participation in EARLY ACS Trial					
Yes, eptifibatide	188	35.16	46.88	0.727 (0.450, 1.176)	0.191
Yes, placebo	174	43.46	32.04	1.381 (0.831, 2.296)	
No	17782	32.58	34.54	0.935 (0.885, 0.987)	

C. Prior LLT Experience, High-risk ACS Diagnosis, and Baseline LDL-C

Characteristic	Total Patients	KM % at 7 years SIMVA/EZE	KM % at 7 years SIMVA	Hazard Ratio (95% CI)	Interaction *P*-Value
Prescription Lipid-Lowering (PLL) Experience					
Prior PLL Therapy at Entry	6434	40.71	43.43	0.903 (0.832, 0.980)	0.272
No PLL Therapy at Entry	11686	28.59	30.04	0.959 (0.893, 1.030)	
Statin Experience					
Statin Therapy at Entry	6246	41.31	43.76	0.910 (0.838, 0.988)	0.414
No Statin Therapy at Entry	11878	28.50	30.13	0.952 (0.887, 1.022)	
High-risk ACS Diagnosis					
NSTE-ACS	12941	34.62	36.59	0.939 (0.881, 1.000)	0.862
STEMI	5190	28.89	31.03	0.929 (0.838, 1.029)	
Baseline LDL-C (mg/dL)					
≤{Median}	9125	35.96	38.43	0.925 (0.860, 0.995)	0.670
>{Median}	8874	29.55	31.15	0.947 (0.874, 1.026)	
Baseline LDL-C (mg/dL)					
1st quartile	4542	38.02	39.80	0.951 (0.859, 1.052)	0.837
2nd quartile	4583	34.01	37.09	0.899 (0.809, 0.998)	
3rd quartile	4424	31.96	32.98	0.958 (0.859, 1.070)	
4th quartile	4450	27.14	29.38	0.932 (0.829, 1.048)	
Baseline LDL-C (mg/dL) by PLL Therapy Experience Prior PLL Therapy					
≤{Median}	5260	40.58	43.85	0.888 (0.811, 0.971)	0.492
>{Median}	1130	41.03	42.06	0.973 (0.799, 1.184)	



D. No prior LLT, Baseline HDL-C, TG, Non-HDL-C and CRP, and REACH Risk Score



Number of primary composite endpoints were summarized per subgroup within each treatment. Hazard ratios were computed within each subgroup level for treatment effect of Simva/EZE vs. Simva. The p-value resulted from an interaction test in the overall population for treatment by subgroup.

Supplementary Tables

Table S1. Lipid Analyses: Actual Values at Baseline and 1 Year with ANCOVA Model Results

	Baseline	1 Year	Least Squares Estimate Mean at 1 year (LCLM, UCLM)	Least Squares Estimate Difference in Means at 1 year (LCLM, UCLM)	p-value
LDL-Cholesterol - mg/dL (all subjects)					
Simvastatin					
N	9009	6939			
Mean	93.8	69.9			
Median (25th, 75th)	95.0 (79.0, 110.2)	67.0 (55.0, 81.0)			
ANCOVA Model Results (a)			71.8 (70,73.6)		
Ezetimibe/Simvastatin					
N	8990	6864			
Mean	93.8	53.2			
Median (25th, 75th)	95.0 (79.0, 110.0)	50.0 (39.0, 62.0)			
ANCOVA Model Results (a)			55.04 (53.23,56.85)	-16.75 (-17.49,-16.02)	<0.001
Non-HDL-Cholesterol - mg/dL					
Simvastatin					
N	8899	6427			
Mean	120.5	97.1			
Median (25th, 75th)	120.0 (102.0, 138.0)	93.0 (79.0, 110.0)			
ANCOVA Model Results (a)			100.4 (98.12,102.69)		
Ezetimibe/Simvastatin					
N	8894	6368			
Mean	120.5	77.2			
Median (25th, 75th)	120.0 (103.0, 138.0)	72.0 (60.0, 88.0)			
ANCOVA Model Results (a)			80.45 (78.15,82.75)	-19.95 (-20.86,-19.03)	<0.001
Apolipoprotein-B - mg/dL					
Simvastatin					
N	8884	7263			
Mean	92.7	81.3			
Median (25th, 75th)	91.0 (78.0, 106.0)	79.0 (67.0, 93.0)			
ANCOVA Model Results (a)			83.24 (81.74,84.75)		
Ezetimibe/Simvastatin					
N	8861	7204			
Mean	92.7	70.3			
Median (25th, 75th)	91.0 (78.0, 106.0)	67.0 (56.0, 81.0)			
ANCOVA Model Results (a)			72.12 (70.6,73.63)	-11.13 (-11.74,-10.51)	<0.001

	Baseline	1 Year	Least Squares Estimate Mean at 1 year (LCLM, UCLM)	Least Squares Estimate Difference in Means at 1 year (LCLM, UCLM)	p-value
Total Cholesterol - mg/dL					
Simvastatin					
N	9000	6950			
Mean	162.6	145.1			
Median (25th, 75th)	162.4 (144.0, 181.0)	142.0 (126.0, 160.0)			
ANCOVA Model Results (a)			148.02 (145.79,150.26)		
Ezetimibe/Simvastatin					
N	8998	6878			
Mean	162.7	125.8			
Median (25th, 75th)	162.4 (144.0, 181.0)	121.0 (107.0, 139.0)			
ANCOVA Model Results (a)			128.68 (126.43,130.92)	-19.34 (-20.26,-18.43)	<0.001
Triglycerides - mg/dL (b)					
Simvastatin					
N	8951	6950			
Mean	137.5	137.1			
Median (25th, 75th)	121.0 (85.0, 172.0)	116.0 (84.0, 165.0)			
ANCOVA Model Results (b)			125.61 (121.51,129.86)		
Ezetimibe/Simvastatin					
N	8954	6878			
Mean	137.6	120.4			
Median (25th, 75th)	120.0 (85.0, 172.0)	104.0 (77.0, 143.0)			
ANCOVA Model Results (b)			111.57 (107.91,115.37)	-14.04 (-15.71,-12.37)	<0.001
HDL-Cholesterol - mg/dL					
Simvastatin					
N	8930	6942			
Mean	42.2	48.1			
Median (25th, 75th)	40.0 (33.0, 49.0)	46.0 (39.0, 55.0)			
ANCOVA Model Results (a)			47.83 (47.06,48.61)		
Ezetimibe/Simvastatin					
N	8929	6871			
Mean	42.1	48.7			
Median (25th, 75th)	40.0 (33.0, 49.0)	47.0 (40.0, 56.0)			
ANCOVA Model Results (a)			48.51 (47.73,49.29)	0.67 (0.36,0.99)	<0.001

	Baseline	1 Year	Least Squares Estimate Mean at 1 year (LCLM, UCLM)	Least Squares Estimate Difference in Means at 1 year (LCLM, UCLM)	p-value
hs-CRP - mg/dL(b)					
Simvastatin					
N	8871	7019			
Mean	21.5	3.8			
Median (25th, 75th)	9.5 (4.0, 26.4)	1.6 (0.8, 3.6)			
ANCOVA Model Results (b)			1.76 (1.61,1.92)		
Ezetimibe/Simvastatin					
N	8849	6954			
Mean	22.1	3.3			
Median (25th, 75th)	9.6 (3.9, 26.7)	1.3 (0.6, 2.8)			
ANCOVA Model Results (b)			1.43 (1.31,1.56)	-0.33 (-0.39,-0.27)	<0.001

(a) LS means, difference in LS means, 95% CI, and p-values are based on ANCOVA models at 1 year with covariates of the stratification factors (EARLY ACS trial, prior
lipid-lowering experience, and high-risk ACS diagnosis), baseline value and treatment.

(b) LS means, difference in LS means, 95% CI, and p-values are based on ANCOVA models at 1 year with factors for log transformed baseline value, treatment, and stratification
factors (participation in EARLY ACS trial, prior lipid-lowering experience, and high-risk ACS diagnosis). LS Means are geometric means calculated based on back-transformation via exponentiation of the model-based least squares means, and SEs are calculated using delta method.

Baseline levels measured at the time of qualifying index ACS event with the exception of hs-CRP were the value closest to randomization was used. Levels represented as mean, median and interquartile range. Percent changes from baseline are model-based from ANCOVA with terms for treatment, baseline value, and the stratification factors. Since hs-CRP and triglycerides are not normally distributed, natural log transformations were used to meet analysis of covariance assumptions. The least squares means for these two measures are geometric means based on exponentiation of the model estimates. There are no significant differences in baseline values for all variables between randomized treatment group. LDL denotes low-density lipoprotein cholesterol, HDL high-density lipoprotein cholesterol and hs-CRP high sensitivity C-reactive protein. To convert values for cholesterol to millimoles per liter, multiply by 0.02586. To convert values for triglycerides to millimoles per liter, multiply by 0.01129. To convert values for hs-CRP to nanomoles per liter, multiply by 9.524.

Table S2: Dual Goal of reduction of LDL-C <70 mg/dl and hs-CRP <2.0 at one month

	Simvastatin	Ezetemibe/simvastatin	P value
Dual goal of LDL-C <70 mg/dl and hs-CRP <2.0 at one month (N, %)	2518/8257 (30.5%)	4134/8178 (50.6%)	<0.001