Call for Letter of Intent for Participation in: A Phase II, Open Label, Randomized Controlled Study to Assess the Safety and Efficacy of Convalescent Plasma to Limit COVID-19 Associated Complications

Disclaimer

Convalescent Plasma is an experimental procedure for COVID-19 patients. Hospitals and Institutions planning to provide this modality of treatment should do so in a clinical trial with protocols which are cleared by the Institutional Ethics Committee. The protocols should be: -

1. Registered with the Clinical Trial Registry of India (CTRI: http://ctri.nic.in/Clinicaltrials/login.php).
2. They should be approved by Drugs Controller General of India, Central Drugs Standard Control Organization (https://cdsco.gov.in/opencms/opencms/en/Home).
3. Mechanisms to report adverse and serious adverse events to the CDSCO should be put in place.

At this moment ICMR does not recommend this as a treatment option outside of clinical trials.

ICMR is inviting a letter of intent from institutions with the equipment and infrastructure available to participate in a clinical trial to study the safety and efficacy of convalescent plasma in COVID-19 patients, subsequent to necessary approvals and clearances.

Institutions which are interested to collaborate with ICMR on undertaking this trial intervention, may express their interest by providing the details through the following link: https://forms.gle/fZvhKuyaTAgLjY1SA

For further details please contact:

Dr. Anup Agarwal

Email: mailanupagarwal@gmail.com

A Phase II, Open Label, Randomized Controlled Study to Assess the Safety and Efficacy of Convalescent Plasma to Limit COVID-19 Associated Complications

Primary Objectives

- To assess the efficacy of convalescent plasma to limit complications in COVID-19 patients.
- To evaluate the safety of treatment with anti SARS-CoV-2 plasma in patients with COVID-19.

Study Design

- Multi centric, two arm, prospective, phase II, open label, randomized controlled trial.

Study Population

- Hospitalized COVID-19 patients fulfilling the inclusion and exclusion criteria, and admitted for care at COVID-19 management facilities in India will be eligible for inclusion in the trial.

Intervention

- Convalescent serum, retrieved from patients who have recovered from a documented episode of COVID-19 infection, with complete resolution of symptoms, and laboratory confirmed to be negative for COVID-19.

Primary Outcomes

- Composite primary outcome of avoidance of progression to severe disease and death.

For more technical details, please contact:

Dr. Anup Agarwal
Email: mailanupagarwal@gmail.com