

Call for Letter of Intent for Participation in: Therapeutic Plasma Exchange in COVID-19: Protocol for a Multi-center, Phase II, Open Label, Randomized Controlled Study

Disclaimer

Therapeutic Plasma Exchange (TPE) is an experimental procedure for critically ill 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 therapeutic plasma exchange 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/7AaW528DMQbNZsUr9>

For further details please contact:

Dr. Anup Agarwal

Email: mailanupagarwal@gmail.com

Therapeutic Plasma Exchange in COVID-19: Protocol for a Multi-center, Phase II, Open Label, Randomized Controlled Study

Primary Objectives

- To assess the efficacy of TPE in improving the clinical status of 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 who are critically ill, fulfill the inclusion and exclusion criteria, and are admitted for care at COVID-19 management facilities in India will be eligible for inclusion in the trial.

Intervention

- Therapeutic plasma exchange for critically ill COVID-19 patients

Primary Outcomes

- Composite primary outcome of improvement in clinical status and respiratory support needed.

For further technical details, please contact:

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