ICMR’s clearance on using convalescent plasma therapy

Context

The U.S. FDA and India’s ICMR have approved the use of plasma from recovered COVID-19 patients only for trial purposes.

With the ethics committee approval in hand on May 8, the ICMR cleared the last hurdle to conduct a **multicentric phase-2 trial** using convalescent plasma on COVID-19 patients with **moderate illness**.

**Phase 2 trial- to check the efficacy of Plasma therapy**

- Its three feasibility studies in about 20 severely ill patients found the **therapy to be safe** and able to **resolve illness or improve the clinical symptoms**.
- Since **safety of convalescent plasma** from people who have recovered from COVID-19 illness is **not a huge concern**, the **first stage of the human clinical trial has been skipped**; the ICMR will instead study plasma safety and efficacy in a phase-2 trial with 452 patients.
- The patients with moderate COVID-19 illness will be randomly assigned to receive either convalescent plasma (226 participants) or only standard of care (control group).
- The primary outcomes of the trial in 21 hospitals that will be studied include prevention of illness from progressing to a severe form, and avoidance of deaths from all causes at **28 days after plasma infusion**.
- And key secondary outcomes will include **resolution of symptoms, reduction in hospital stay and respiratory support**.
- Plasma will be **collected from donors 28 days** after they make a **complete recovery** from illness or are symptom-free and have more than the required level of antibodies against the novel coronavirus.
- **Molecular and also other routine tests** will be done before plasma use.

**Convalescent plasma therapy**

Convalescent plasma therapy, about a **century old**, has shown some benefit in treating **measles, chickenpox and rabies**.

Small studies have shown **faster clearance of virus in the case of MERS and SARS** if given **early in the course** of the disease.

**Issues in Convalescent plasma therapy**

- **No randomised controlled** studies have been carried out.
- **No benefit was seen in 2015 on some Ebola patients** treated with convalescent plasma in Guinea.
- **Only three small studies involving 21 COVID-19 patients have been carried out** but not in trials where the participants were randomised with a control arm.
- Till date, there is a dearth of randomised controlled trials that clearly demonstrate the efficacy of convalescent plasma therapy for any infectious disease, including COVID-19.

**Way Ahead**
Even in the absence of any effective treatment or a vaccine, the pandemic provides an opportunity to ascertain the clinical benefits of plasma therapy through randomised controlled trials.

The ICMR’s insistence on an evidence-based approach to plasma therapy is in contrast to the cavalier manner in which it approved the anti-malarial hydroxychloroquine, as a prophylaxis (treatment given or action taken to prevent disease) for coronavirus without carrying out any trial and relying on evidence that was slim and intended only for treatment, and also when the risks were unknown.

If the trial outcomes are overwhelmingly positive, the agency would be ethically obliged to recommend plasma therapy as a standard of care for COVID-19 patients.