ICMR's Trial on Plasma Therapy

Why in news?

ICMR approved a multi centric phase-2 trial to use convalescent plasma on Covid-19 patients with moderate illness.

Why ICMR will conduct a phase-2 trial?

- **Previously** - ICMR conducted three feasibility studies in about 20 severely ill patients.
- These tests have found the therapy to be safe and able to resolve illness or improve the clinical symptoms.
- **Currently** - Safety of convalescent plasma from people who have recovered from Covid-19 illness is not a huge concern.
- Therefore, 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.

How will the trial be carried out?

- The patients with moderate Covid-19 illness will be randomly assigned to receive either convalescent plasma or only standard of care.
- Plasma will be collected from donors in 21 hospitals, 28 days after they make a complete recovery from illness.
- Or the plasma will be collected from a symptom-free person who have more than the required level of antibodies against the novel coronavirus.
- Molecular and also other routine tests will be done before plasma use.

What will be the outcomes of the new trial?

- The primary outcomes of the trial include,
    1. Preventing the illness from progressing to a severe form, and
    2. Avoiding deaths from all causes at 28 days after plasma infusion.
- Key secondary outcomes will include resolution of symptoms, reduction in hospital stay and respiratory support.

How effective is the CP therapy?

- Convalescent plasma (CP) therapy, about a century old, has shown some

benefit in treating measles, chickenpox and rabies.

- Studies have shown faster clearance of virus in the case of MERS and SARS if given early in the course of disease, but not in randomised trials.
- Only 3 studies involving 21 Covid-19 patients have been carried out but not in trials that will demonstrate the efficacy of CP therapy for Covid-19.

Why trials are important?

- In trials, the participants will be selected randomly with a control arm.
- Randomised controlled trials will clearly demonstrate the efficacy of a therapy for any infectious disease, including Covid-19.
- The pandemic provides an opportunity to **ascertain the clinical benefits** of CP therapy through randomised controlled trials.
- The U.S. FDA and India have thus approved the use of plasma from recovered Covid-19 patients only for trial purposes.

What is next?

- ICMR is following an evidence-based approach to insist on CP therapy.
- If the trial outcomes are positive, the agency would be ethically obliged to recommend CP therapy as a standard of care for Covid-19 patients.

Source: The Hindu