Higher vs. Lower Doses of Dexamethasone in Patients with COVID-19 and Severe Hypoxia: the COVID STEROID 2 trial

Objective

To assess the effects of higher (12 mg) vs. lower doses (6 mg) of intravenous dexamethasone on the number of days alive without life-support in adult patients with COVID-19 and severe hypoxia.

Inclusion criteria

- Aged 18 years or above **AND**
- Confirmed SARS-CoV-2 (COVID-19) requiring hospitalization **AND**
- One of the following:
    - Invasive mechanical ventilation **OR**
    - Non-invasive ventilation or continuous use of CPAP for hypoxia **OR**
    - Oxygen supplementation with an oxygen flow of at least 10 L/min independent of delivery system

Exclusion criteria

- Use of systemic corticosteroids for other indications than COVID-19 in doses higher than 6 mg dexamethasone equivalents **OR**
- Use of systemic corticosteroids for COVID-19 for 5 consecutive days or more **OR**
- Invasive fungal infection **OR**
- Active tuberculosis **OR**
- Fertile woman (<60 years of age) with positive urine human gonadotropin (hCG) or plasma-hCG **OR**
- Known hypersensitivity to dexamethasone **OR**
- Previously randomised into the COVID STEROID 2 trial **OR**
- Informed consent not obtainable **OR**

In case of any questions, contact following individuals:

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Unblinded staff: +918073620654 (Nikita Bathla)

Interventions

Intravenous bolus injection (5 ml) of 12 mg or 6 mg of dexamethasone every 24 hours for up to 10 days.

Top-up procedure

A patient can still be screened if s/he has received up to 8 mg of dexamethasone phosphate or oral dexamethasone on the day of screening:

1. Stop the regular dexamethasone
2. Screen and randomise the patient
3. The unblinded trial staff will prepare a bolus injection of either 5 ml isotonic saline (allocation 6 mg) or 6 mg of dexamethasone (allocation 12 mg) on the day of screening. The trial participant will receive 6 or 12 mg of dexamethasone according to the allocation for the remaining days of the intervention period