Place in Site Master File #10d



Procedure for trial medication preparation if the patient has already received dexamethasone on the day of screening

If the patient has received 6.7 mg of intravenous (IV) betamethasone (corresponding to 8.9 mg betamethasone sodium phosphate) or less OR

If the patient has received 8 mg of per oral (PO) betamethasone or less

- 1. Stop the regular betamethasone
- 2. Screen, randomise and administer trial medication to the patient today as follows:
 - a. If the patient is randomised to 12 mg: Administer bolus injection of 6 mg betamethasone in isotonic saline (bolus volume 5 ml). Administer bolus injections of 12 mg dexamethasone for the remaining days of the intervention period.
 - b. If the patient is **randomised to 6 mg**: Administer **bolus injection of 5 ml isotonic saline only for this day**. Prepare and administer bolus injections of 6 mg dexamethasone for the remaining days of the intervention period.

If the patient has received more than 6.7 mg of IV betamethasone (corresponding to 8.9 mg betamethasone sodium phosphate) or more than 8 mg of PO betamethasone

- 1. Stop the regular betamethasone
- 2. Screen the patient 12 h (or later) after the last administration of betamethasone; if still eligible, randomise, prepare and administer trial medication to the patient then. Please beware that use of betamethasone for 5 consecutive days or more is an exclusion criterion.

If your site uses another steroid for COVID-19 in clinical practice (e.g. dexamethasone or methylprednisolone), please request a document specific for this drug.