

Trial medication preparation

Place in Site Master File #10d



Trial medication

Betamethasone sodium phosphate (in Sweden: Betapred™, Sobi), 1 bolus injection every 24 hours.

General instructions

Preparation of trial medication must be done by two members of the unblinded trial staff. First, the allocation (dexamethasone 12 mg or 6 mg) is checked by both trial staff in the eCRF. During each preparation, remember to note date, time, signatures, allocation, LOT- and BATCH numbers in the trial medication log.

In Sweden, betamethasone is used instead of dexamethasone and in the same doses as dexamethasone (i.e. 12 mg or 6 mg).

12 mg betamethasone

4 vials of betamethasone sodium phosphate (5.3 mg betamethasone sodium phosphate per vial corresponding to 4 mg betamethasone per vial)

1x 10 ml or 20 ml of isotonic saline (0,9%)

1x 5 ml syringe

1x 2 ml syringe

2x needle

1x cork for the syringe

1x trial medication label with patient ID

1 alcohol swap

The following procedure should be witnessed and documented in the trial medication log by two unblinded trial staff members.

1. Note ID, date and allocation (12 mg) in the trial medication log (one log for each patient)
2. Apply hand sanitizer and put on gloves
3. Prepare the syringes by applying the needles
4. Withdraw 3 ml from the 3 vials of betamethasone sodium phosphate into the 5 ml syringe
5. Withdraw 2 ml of isotonic saline into the 2 ml syringe
6. Pull back the plunger to maximum on the 5 ml syringe
7. Inject the 2 ml of isotonic saline into the 5 ml syringe
8. Empty the 5 ml syringe of extra air
9. Visually inspect the solution for opacities
10. Apply cork and trial medication label with patient ID

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11. Apply date and signature for trial medication preparation on the trial medication log (both unblinded trial staff members)
12. Place all needles and other sharps in the disposal container, and discard the remaining waste

6 mg betamethasone

2 vials of betamethasone sodium phosphate (5.3 mg betamethasone sodium phosphate per vial corresponding to 4 mg betamethasone per vial)

1x 10 ml or 20 ml of isotonic saline (0,9%)

1x 5 ml syringe

1x 2 ml syringe

2x needle

1x cork for the syringe

1x trial medication label with patient ID

1 alcohol swap

The following procedure should be witnessed and documented in the trial medication log by two unblinded trial staff members.

1. Note ID, date and allocation (6 mg) in the trial medication log (one log for each patient)
2. Apply hand sanitizer and put on gloves
3. Prepare the syringes by applying the needles
4. Withdraw 1.5 ml from the 2 vials of betamethasone sodium phosphate into the 2 ml syringe
5. Withdraw 3.5 ml of isotonic saline into the 5 ml syringe
6. Pull back the plunger to maximum on the 5 ml syringe
7. Inject the 1.5 ml of betamethasone sodium phosphate into the 5 ml syringe
8. Empty the 5 ml syringe of extra air
9. Visually inspect the solution for opacities
10. Apply cork and trial medication label with patient ID
11. Apply date and signature for trial medication preparation on the trial medication log (both unblinded trial staff members)
12. Place all needles and other sharps in the disposal container, and discard the remaining waste

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Trial medication label

<p style="text-align: center;">COVID STEROID 2 trial medication for clinical trial Betamethasone 12 mg OR betamethasone 6 mg</p> <p>For injection</p> <p>Patient name.....</p> <p>Identification number.....</p> <p>Date and time of preparation of trial medication.....</p> <p>Signature.....</p> <p>Must be stored at ≤ 25 °C</p> <p>Questions? Contact HOTLINE tel. +45 3545 7237</p> <p>Sponsor: Prof. Anders Perner, Dept. of Intensive Care, Rigshospitalet, Denmark. Tel. +45 3545 8333</p>
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