

1. INFUSION

LOADING DOSE - 2 ampoules over 10 minutes

- Give immediately after randomisation
- PRESCRIBE: "CRASH-2 Trial (1 gram of tranexamic acid / placebo) over 10 minutes"
- Using syringe provided in the treatment pack draw up 10 mL (2 ampoules of tranexamic acid / placebo) and add to 100 ml bag of Sodium Chloride 0.9% provided - Mix well
- Fill in date of randomisation on all 6 peelable labels on the cover of the pack
- Peel off a pre-printed INFUSION label and attach to bag
- If required, complete and attach a hospital infusion label to bag
- Connect infusion to patient's IV line and infuse over 10 minutes
- Peel off a pre-printed DRUG CHART label, place at the front of prescription chart and complete drug chart
- Peel off pre-printed randomisation numbers and place one on PATIENT MEDICAL RECORDS, one on ENTRY FORM and one on OUTCOME FORM

MAINTENANCE DOSE - 2 ampoules over 8 hours

- Start immediately after completion of loading dose
 - PRESCRIBE: "CRASH-2 Trial (1 gram of tranexamic acid / placebo). Infuse at 60 mL/hour"
 - Draw up 10 mL (2 ampoules of tranexamic acid / placebo) and add to 500 mL bag of Sodium Chloride 0.9%*
 - Peel off a pre-printed INFUSION LABEL and attach to bag
 - If required, complete and attach a hospital infusion label to bag
 - Connect infusion to patient's IV line and infuse at 60 mL/hour
 - If infusion is terminated early for any reason, please record end time on prescription chart
- * or other fluid for intravenous infusion can be used (e.g Ringer's solution)
- ENSURE PATIENT DETAILS ARE RECORDED ON RANDOMISATION LOG IN THE SITE FILE

2. STOCK OF TREATMENT PACKS

When you are ready to start the trial in your hospital you will initially receive one box containing 8 individual treatment packs. Thereafter, your stock level will depend on your average monthly recruitment rate. Every time you randomise a patient, the database in the Co-ordinating Centre will deduct one pack off your stock. When you reach your minimum level, you will be sent a new box – or boxes – automatically. You don't need to remind us.

NOTE FOR NON-TELEPHONE RANDOMISING CENTRES:
IT IS THEREFORE MOST IMPORTANT THAT YOU SUBMIT THE PATIENT ENTRY FORM AS SOON AS A PATIENT HAS BEEN ENTERED INTO THE TRIAL. THAT IS THE ONLY WAY WE CAN MONITOR YOUR DRUG STOCK LEVEL.

3. EXPIRY

The expiry date of the tranexamic acid and placebo is printed on the glass ampoules. When they are about to expire, we will contact you to tell you what to do and also send you new up to date treatment packs.

If the bag of saline in the treatment pack has expired, please replace it from your hospital stocks and use the treatment pack in the normal way. The expiry of the saline does not in any way invalidate the rest of the treatment pack.





- Box should be received intact
- Please inspect for damage and return Drug Receipt to the Co-ordinating Centre



- For telephone randomisation open this side
- Pack number will be allocated by the Randomisation Service
- Patient entry forms, outcome forms and patient information leaflets are in colour coded envelopes underneath the treatment packs



- For non-telephone randomisation use this side
- Tear off the flap at the bottom section and the lowest pack number will be ready to pull out
- Patient entry forms, outcome forms and patient information leaflets are in colour coded envelopes underneath the treatment packs



- Infusion instructions are inside the lid of the treatment pack – please follow them carefully
- Write the date of randomisation on each one of the blue labels on top of the pack and attach them as instructed



- Please report any lost or damaged treatment packs to crash@Lshtm.ac.uk