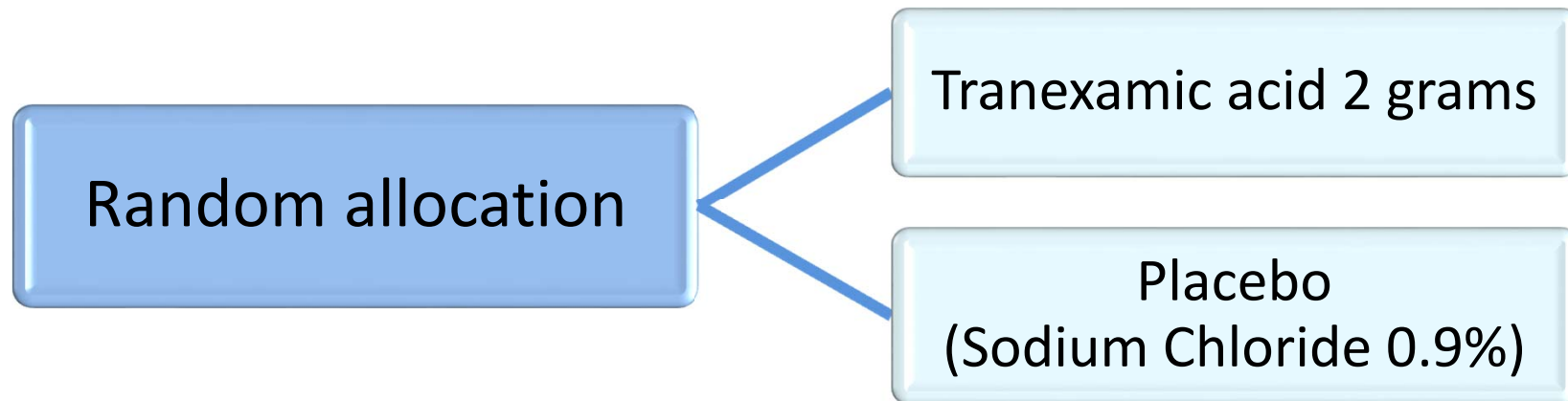


Managing and administering The trial treatment

Protocol Code: ISRCTN15088122
V 1.0 date 30 Jan 2012

What is the trial treatment



Managing stock

- Initial supply: one drug box containing eight individual patient treatment packs
- Thereafter, minimum stock level based on your average monthly recruitment
- When TCC receives entry form the pack is removed from your stock in the trial database
- At minimum level we will automatically send a new box/boxes – no need to remind us
- We can monitor your drug stock level **ONLY** if you send the entry form (within 24 hours of randomisation)
- PI or his/her delegate is responsible for accounting for every pack of trial treatment sent to your hospital

Packs		
Number	Status	Date
21	used in trial	6 Jun 2012
22	used in trial	10 Jun 2012
23	unused	
24	unused	
25	unused	
26	unused	
27	unused	
28	unused	

Receiving new supplies

- Box should be received intact
- Inspect for damage
- Sign PART 1 of **Drug Accountability Log** sent with each box, send to TCC by fax or email
- Store securely, but accessible to the trial team for randomisation at all times
Please discuss with your pharmacist responsible for clinical trials if required
- Store in a cool dry place protected from excessive heat and freezing



Do not open individual packs to inspect the contents until used for randomisation!

What is in the box



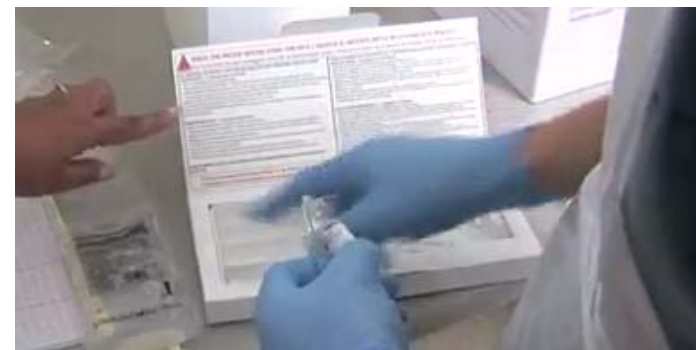
- **Site box** contains:
 - Treatment box
 - 8 x 100mL bags of normal saline for loading dose
- **Treatment box** contains:
 - 8 individual patient treatment packs
- **Treatment pack** contains:
 - 4 x 500mg ampoules of TXA or placebo
 - 2 x sterile 10mL syringe and 21FG needle

- With each drug box you will also receive **envelopes** of:
 - Entry forms
 - Outcome forms
 - Label sheets for recording the treatment
 - Brief information leaflets for family and friends
 - Hospital specific information sheets and consent forms
 - Patient alert cards



Before treatment is given

- Trial treatment to be used only for patients randomised to the CRASH-3 trial – **NOT for any other purpose**
- To assess eligibility, **screening and consent details** on the entry form must be captured before randomising a patient
- **Always use the treatment packs in sequential number order**
- Check **expiry date** before giving the treatment
- Before allocating box/pack number to the patient, check that **all four ampoules are intact** – if any are broken:
 - discard the complete treatment pack
 - take next available number
 - report broken pack on the Drug Accountability Log and **inform TCC**
- The intact pack chosen will be the randomisation number



Trial treatment

TREATMENT	AMPOULES	DOSE TXA / PLACEBO	ADMINISTRATION INSTRUCTION
Loading Dose	2	1 gram	Added to 100mL sodium chloride 0.9% (provided in site box) and infused over 10 minutes
Maintenance Dose	2	1 gram	Added to 500mL of any isotonic intravenous solution and infused at 120mg/hr [60 mL/hr] for about 8 hours

Trial treatment injections should not be mixed with blood for transfusion or infusion solutions containing penicillin or mannitol.



Infusion – Loading dose

Loading dose to be given to all randomised patients

Using syringe provided draw up 10mL (2 ampoules) of TXA/placebo and add to to 100mL normal saline 0.9% (provided) and give as an intravenous infusion over 10 minutes

- Peel off pre-printed yellow randomisation stickers and attach one on each blue form
- Using the pre-printed blue label provided PRESCRIBE: “CRASH-3 trial loading dose (1g of tranexamic acid/ placebo)”
- Place prescription label in the patient’s medical records
- Give immediately after randomisation



**Instructions printed inside the lid of the treatment pack.
Can be provided in local language if required.**

Infusion – Maintenance dose

Maintenance dose to be given to all randomised patients immediately following the loading dose

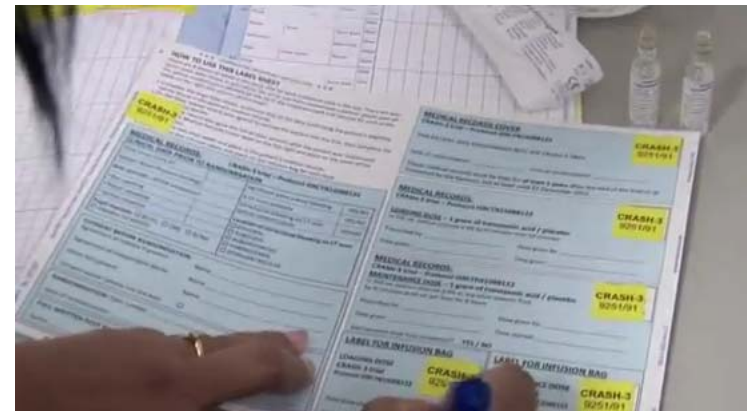
Using syringe provided draw up 10mL (2 ampoules) of TXA/placebo and add to 500mL of any isotonic intravenous solution and infuse over 8 hours

- Using the pre-printed blue label provided PRESCRIBE:
“CRASH-3 trial maintenance dose (1g of tranexamic acid/ placebo)”
- Place prescription label in the patient’s medical records



Labelling

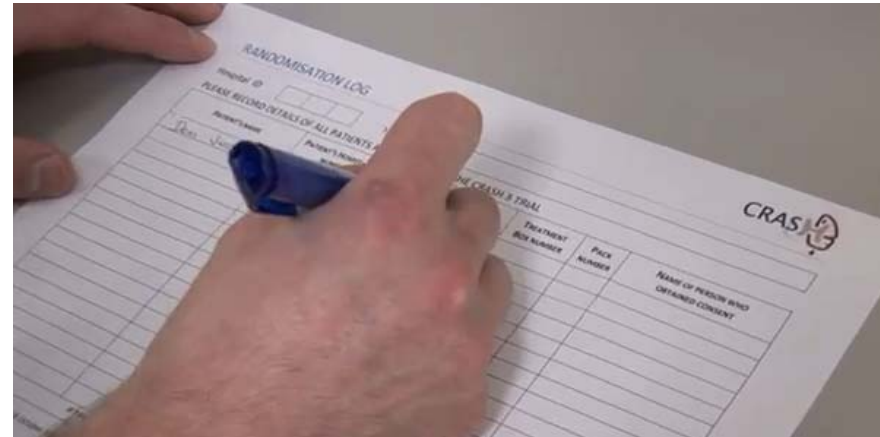
- Peelable stickers with the randomisation number on the lid of each treatment pack
- Presentation titled “Randomising an eligible patient” will give you more details about how to use the labels



**TRANSMIT ENTRY DATA TO TCC
WITHIN 24 HOURS**

Recording the use of packs

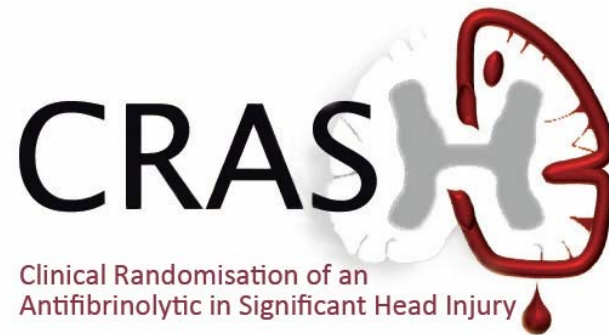
- Remember to update the relevant logs in the Study File
 - Randomisation log
 - Drug Accountability log Part 2



**SIGN THIS PART WHEN ALL PACKS HAVE BEEN ACCOUNTED FOR,
THEN FAX OR EMAIL TO TCC AGAIN**

PART 2: DRUG ACCOUNTABILITY

BOX	PACK	Date randomised (please send entry form)	Damaged?	Lost?	Destroyed?
9251	91	<i>15/05/2012</i>			
9251	92				
9251	93				



Trial Coordinating Centre

London School of Hygiene & Tropical Medicine

Room 180, Keppel Street, London WC1E 7HT

Tel +44(0)20 7299 4684 | Fax +44(0)20 7299 4663

crash@Lshtm.ac.uk

crash3.Lshtm.ac.uk

