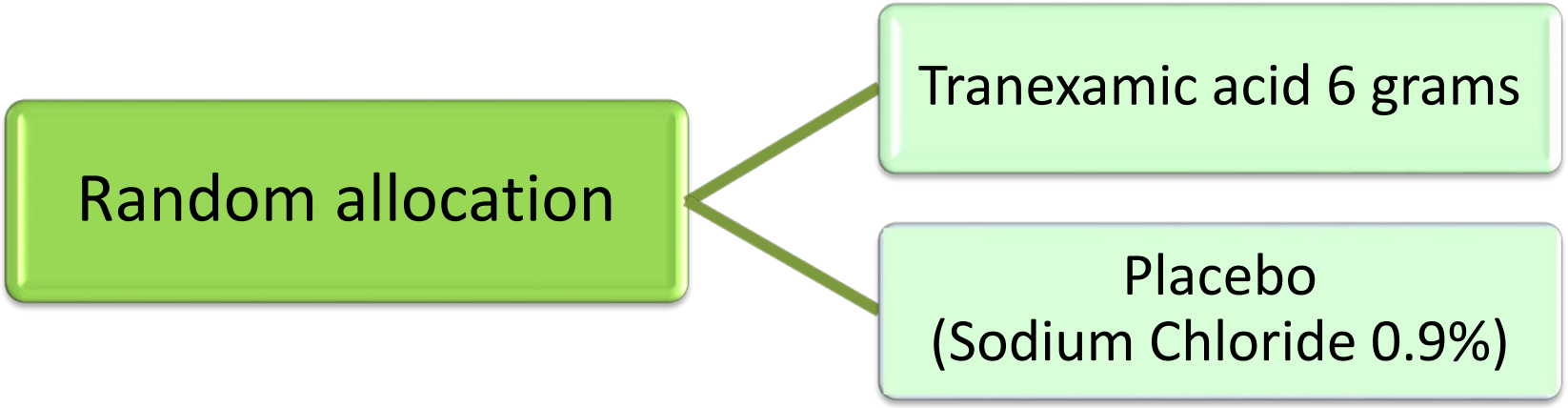
Haemorrhage alleviation with tranexamic acid - Intestinal system

HOW TO MANAGE AND ADMINISTER THE TRIAL TREATMENT

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 an 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

Packs

Number	Status	Date
11	used in trial	1 May 2013 13:20
12	used in trial	8 May 2013 12:00
13	unused	
14	unused	
15	unused	
16	unused	
17	unused	
18	unused	

- 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

Receiving new supplies

- Box should be 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 at all times – Please discuss with your pharmacist responsible for clinical trials if required

Site box

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

What is in the site 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:
  - 8 x 500mg ampoules of TXA or placebo
  - 2 x sterile 10mL syringe and 21FG needle

Site box

100mL bags of normal saline for loading dose

Treatment box

Treatment pack

Documents with the site box

With each drug box you will also receive envelopes of:

- Entry forms
- Outcome forms
- Label sheets for recording the treatment
- Brief information leaflets
- Patient information sheets and consent forms
- Patient alert cards

Before treatment is given

- Trial treatment is only for patients randomised to the HALT-IT trial
- Check expiry date
- Use treatment packs in sequential number order
- Before allocating box/pack number to the patient, check that all eight ampoules are intact – if not:
  - discard the treatment pack
  - take next available pack
  - report broken pack on Drug Accountability Log
  - inform TCC

Trial treatment

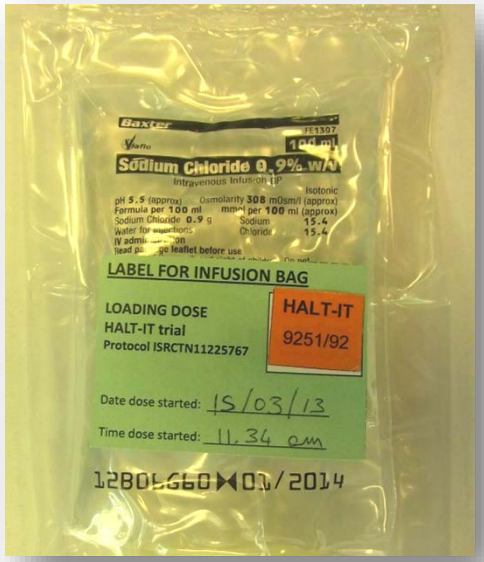
TREATMENT	AMPOULES	DOSE (TXA OR PLACEBO)	ADMINISTRATION
Loading dose	2	1 gram	Added to 100 mL sodium chloride 0.9% and infused over 10 minutes.
Maintenance dose	6	3 grams	Added to 1,000 mL of any isotonic intravenous solution and infused at 125 mg/hr [42 mL/hr] for about 24 hours.
The trial treatment 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 10 mL (2 ampoules) of TXA/placebo and add to the 100 mL bag of sodium chloride 0.9% provided.

- Peel off pre-printed orange randomisation stickers and attach one on each green label
- Using the pre-printed green label provided PRESCRIBE: *"HALT-IT trial (1 gram of tranexamic acid/placebo in 100 mL sodium chloride 0.9% by IV infusion over 10 minutes)"*.
- Place prescription label in the patient's medical records
- Attach an infusion label to the bag.
- Give immediately after randomisation



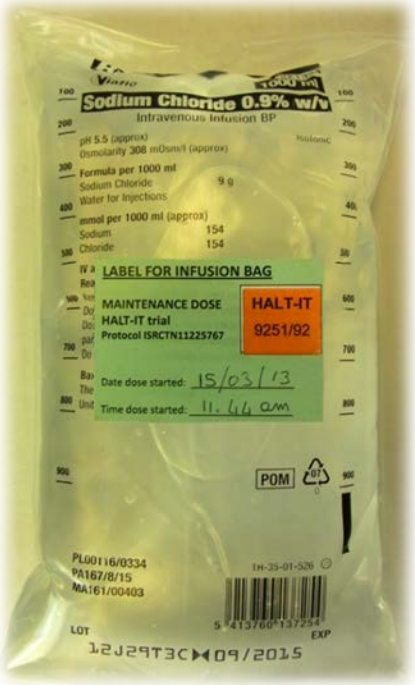
Instructions printed inside the lid of the treatment pack. Can be provided in local language if required.

Infusion – Maintenance dose

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

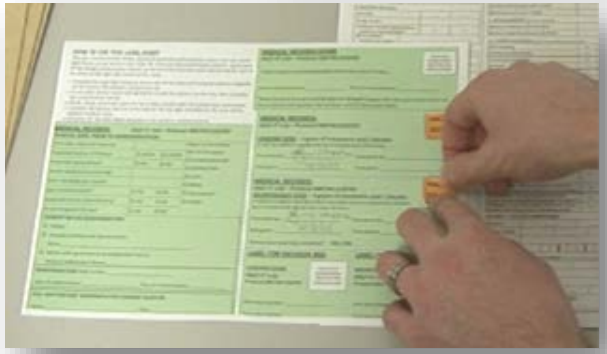
Using the second syringe provided, draw up 30 mL (6 ampoules) of TXA/placebo and add to 1000 mL sodium chloride 0.9% or any isotonic intravenous solution.

- Using the pre-printed green label provided PRESCRIBE:
  "HALT-IT trial (3 grams of tranexamic acid/placebo in 1000 mL sodium chloride 0.9% or any other isotonic intravenous solution by IV infusion at 42 mL per hour for 24 hours)".
- Connect infusion to patient's IV line and infuse at 42 mL per hour for about 24 hours.
- Record end time on prescription chart.



Labelling

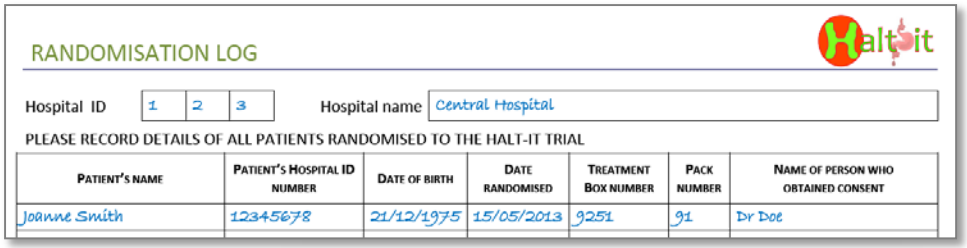
- Peelable stickers with the box/pack number are on the lid of each treatment pack
- Presentation titled "How to randomise an eligible patient" will give you more details about how to use the labels



SEND 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

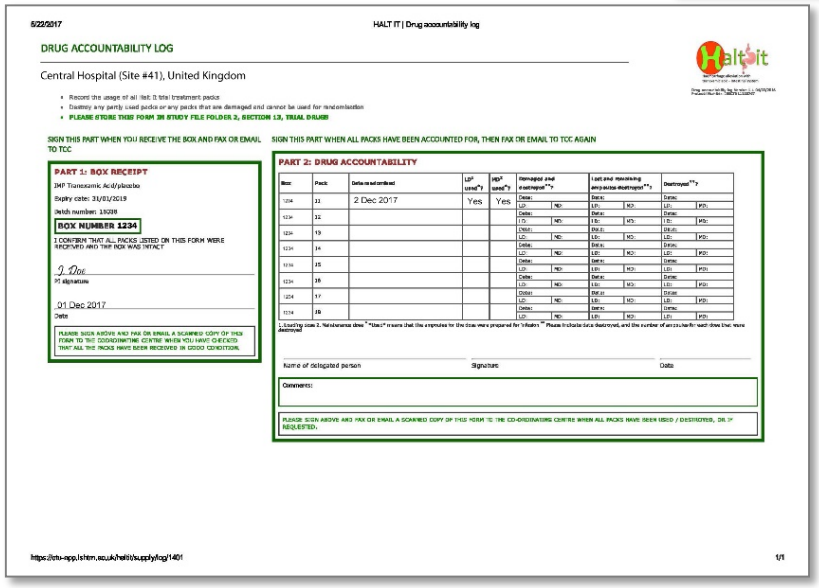


RANDOMISATION LOG

Hospital ID: 1 2 3 Hospital name: Central Hospital

PLEASE RECORD DETAILS OF ALL PATIENTS RANDOMISED TO THE HALT-IT TRIAL

Patient's name	Patient's Hospital ID number	Date of birth	Date randomised	Treatment Box number	Pack number	Name of person who obtained consent
Joanne Smith	12345678	21/12/1975	15/05/2013	9251	91	Dr Doe



5/22/2017 HALT IT | Drug accountability log

DRUG ACCOUNTABILITY LOG

Central Hospital (Site #41), United Kingdom

- Record the usage of all Halt It trial treatment packs
- Destroy any partly used packs or any packs that are damaged and cannot be used for randomisation
- PLEASE STORE THIS FORM IN STUDY FILE FOLDER 2, SECTION 13, TRIAL DRUGS

SIGN THIS PART WHEN YOU RECEIVE THE BOX AND FAX OR EMAIL TO TCC

PART 1: BOX RECEIPT

IMP Tranexamic Acid/placebo

Supply date: 31/01/2013

Batch number: 13038

BOX NUMBER 1234

I CONFIRM THAT ALL PACKS LISTED ON THIS FORM WERE RECEIVED AND THIS BOX WAS INTACT

J. Doe
PI signature

01 Dec 2017
Date

PLEASE SIGN ABOVE AND FAX OR EMAIL A SCANNED COPY OF THIS FORM TO THE COORDINATING CENTRE WHEN YOU HAVE CHECKED THAT ALL THE PACKS HAVE BEEN RECEIVED IN GOOD CONDITION.

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

PART 2: DRUG ACCOUNTABILITY

Box	Pack	Date received	LD used	MD used	Damaged and destroyed	Lost and remaining at site at destruction	Destroyed
1234	11	2 Dec 2017	Yes	Yes	Date: LD: MD:	Date: LD: MD:	Date: LD: MD:
1234	12				Date: LD: MD:	Date: LD: MD:	Date: LD: MD:
1234	13				Date: LD: MD:	Date: LD: MD:	Date: LD: MD:
1234	14				Date: LD: MD:	Date: LD: MD:	Date: LD: MD:
1234	15				Date: LD: MD:	Date: LD: MD:	Date: LD: MD:
1234	16				Date: LD: MD:	Date: LD: MD:	Date: LD: MD:
1234	17				Date: LD: MD:	Date: LD: MD:	Date: LD: MD:
1234	18				Date: LD: MD:	Date: LD: MD:	Date: LD: MD:

Name of delegated person Signature Date

Comments:

PLEASE SIGN ABOVE AND FAX OR EMAIL A SCANNED COPY OF THIS FORM TO THE CO-ORDINATING CENTRE WHEN ALL PACKS HAVE BEEN USED / DESTROYED, OR IF REQUESTED.

https://ctu-app.lshtm.ac.uk/halt/supplylog/1401 1/1

JOIN THE GLOBAL COLLABORATION

haltit.Lshtm.ac.uk

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Haltit
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