Haemorrhage alleviation with tranexamic acid - Intestinal system

HOW TO RANDOMISE AN ELIGIBLE PATIENT

Randomisation process

If the patient is eligible and the informed consent process has been completed, they should be RANDOMISED as soon as possible

- Use one box at a time
- Check the expiry date
- Take the lowest numbered pack from the treatment box of 8 packs

Randomisation process

- ALWAYS use the treatment packs in sequential order starting with the LOWEST NUMBER
  i.e. 1001/11 must be used before 1001/12
- **DO NOT SKIP numbers!**
- Open the pack and check that all the ampoules are intact
- Complete the Entry form questions 20–23
  – eligibility has already been confirmed by completing questions 1–19

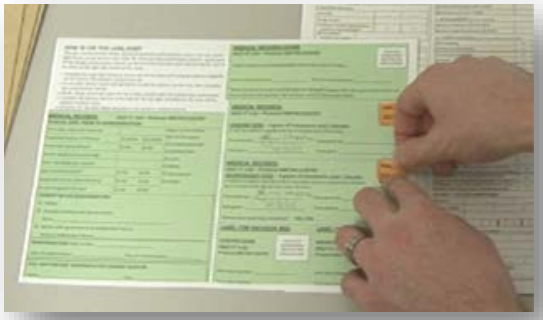
When is a patient randomised?

- The box/pack number is officially assigned when all eight ampoules are found to be intact.
- Record box/pack number on ENTRY form
- From this point, the ENTRY form and OUTCOME form must be sent to the TCC even if the patient does not receive the trial treatment, or if later they are found to be ineligible.

Labels

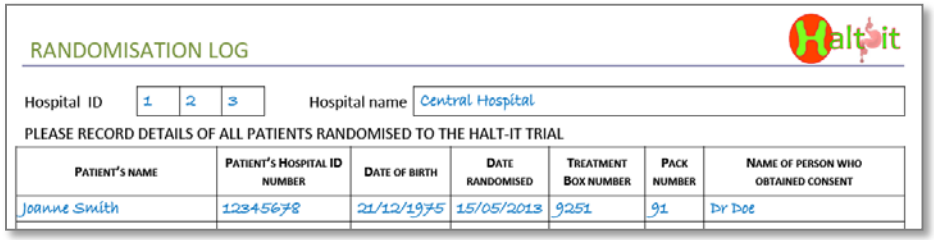
The pre-numbered stickers and pre-printed labels will help you to record the randomisation details accurately on all necessary documents and in the patient's medical notes.

- Place one of the orange randomisation stickers from the pack lid on each of the green labels
- Complete the green label MEDICAL RECORDS with the eligibility, consent and randomisation data and place in the patient's medical notes
- Complete the green label MEDICAL RECORDS COVER and place on the front of the medical notes
- Fill in the two green prescription labels and place in the medical notes (one for each dose given)
- Fill in the two green infusion labels and place one on each infusion bag



Documenting the randomisation

- Record the patient on the Randomisation Log and the drug allocation on the Drug Accountability log.
- Send the entry data to the TCC within 24 hours of randomisation

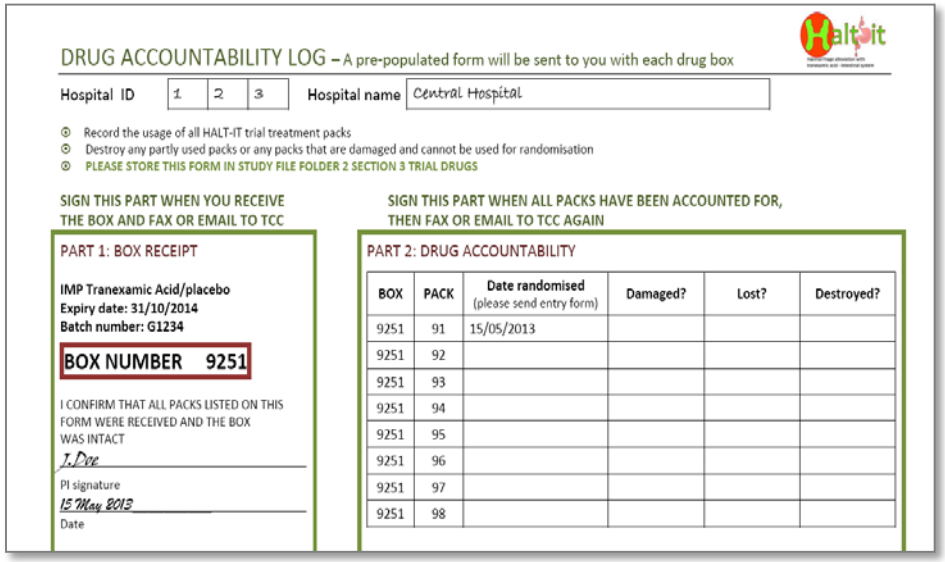


RANDOMISATION LOG

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



DRUG ACCOUNTABILITY LOG – A pre-populated form will be sent to you with each drug box

Hospital ID: 1 2 3 Hospital name: Central Hospital

- 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 3 TRIAL DRUGS

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

PART 1: BOX RECEIPT

IMP Tranexamic Acid/placebo
Expiry date: 31/10/2014
Batch number: G1234

BOX NUMBER 9251

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

J Doe
PI signature

15 May 2013
Date

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	15/05/2013			
9251	92				
9251	93				
9251	94				
9251	95				
9251	96				
9251	97				
9251	98				

JOIN THE GLOBAL COLLABORATION

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