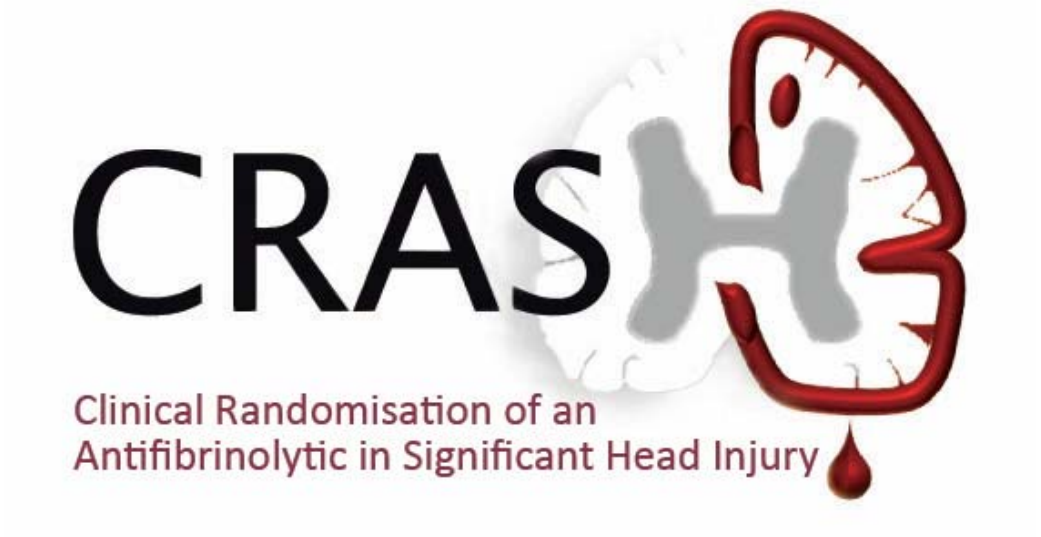


How to randomise an eligible patient

Protocol Code: ISRCTN15088122
V 1.0 date 30 Jan 2012

Randomisation process

If a patient is eligible for the trial and informed consent process completed (eg waiver or agreement), they should be RANDOMISED as soon as possible

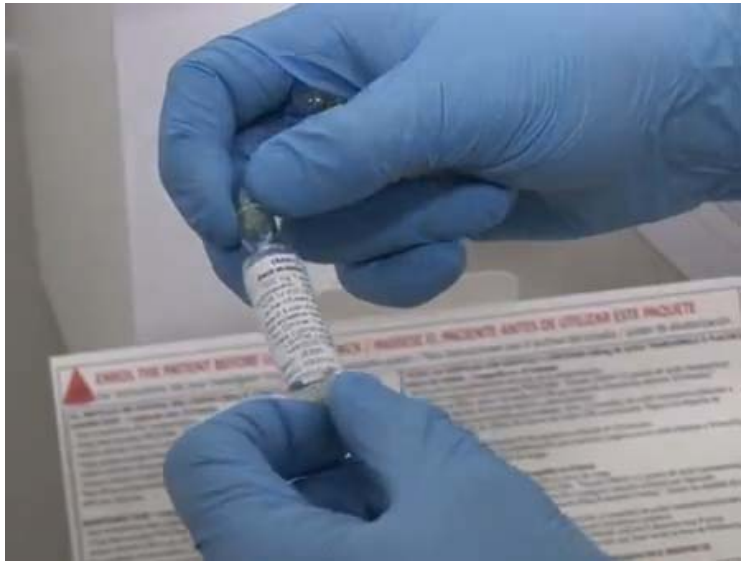
- Use one box at a time
- Take the next lowest numbered treatment pack from the box of 8 packs

Randomisation process

- ALWAYS use the treatment packs in sequential order starting with the LOWEST NUMBER
  eg 4001/41 must be used before 4001/42
- **DO NOT SKIP numbers!**
  This will break the randomisation sequence.
- Open the pack and check that all the ampoules are intact
- Complete the Entry form questions 17–21
  – eligibility has already been confirmed by completing questions 1–16

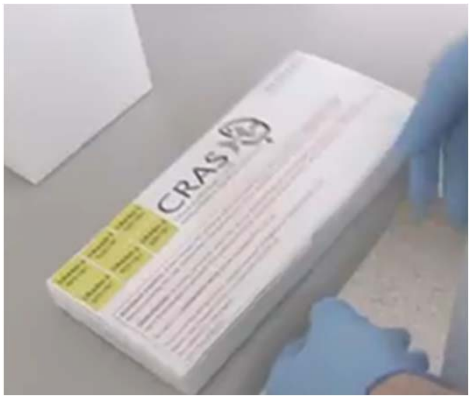
When is a patient randomised?

- The randomisation number is officially assigned at the point when all four ampoules are found to be intact.
- Record randomisation number on ENTRY form
- From this point onwards, the ENTRY form and OUTCOME form must be sent to the TCC even if the patient does not receive any of the trial treatment, or if subsequently they are found to be not eligible.

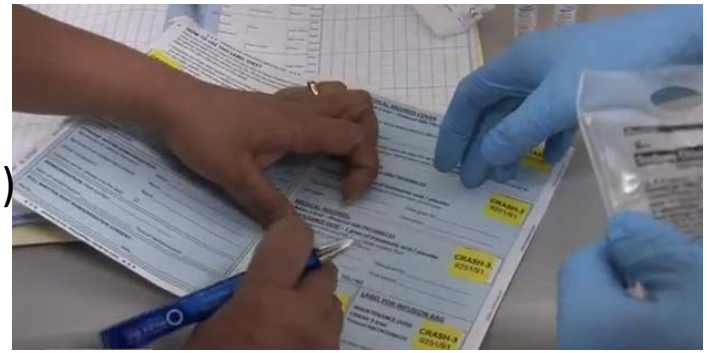


Labels

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



Documenting the randomisation

- Record the randomisation on the Randomisation Log and the drug allocation on the Drug Accountability log.
- Transmit the entry data to the TCC as soon as possible but within 24 hours after randomisation

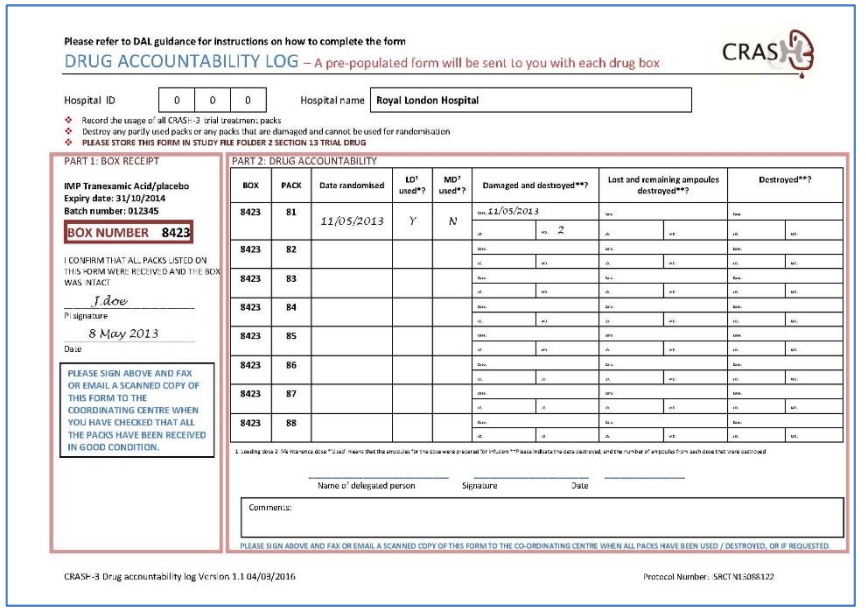
RANDOMISATION LOG

CRASH-3

Hospital ID 0 0 0 Hospital name *Royal London Hospital*

PLEASE RECORD DETAILS OF ALL PATIENTS RANDOMISED TO THE CRASH-3 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
Sean Smith	*X123*	*23/01/87*	*15/05/12*	*9251*	*91*	*Tim Harris*



Please refer to DAL guidance for instructions on how to complete the form

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

CRASH-3

Hospital ID 0 0 0 Hospital name **Royal London Hospital**

- Record the usage of all CRASH-3 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 DRUG**

PART 1: BOX RECEIPT

IMP Tranexamic Acid/placebo
Expiry date: 31/10/2014
Batch number: 012345

BOX NUMBER 8423

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

J doe
PI signature

8 May 2013
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.

PART 2: DRUG ACCOUNTABILITY

BOX	PACK	Date randomised	LD† used*?	MD† used*?	Damaged and destroyed**?	Lost and remaining ampoules destroyed**?	Destroyed**?
8423	81	*11/05/2013*	*Y*	*N*	*11/05/2013*		
8423	82						
8423	83						
8423	84						
8423	85						
8423	86						
8423	87						
8423	88						

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.

CRASH-3 Drug accountability log Version 1.1 04/03/2016 Protocol Number: ISRCTN15088122

CRASH

Clinical Randomisation of an Antifibrinolytic in Significant Head Injury

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

UKCRC Registered Clinical Trials Units