CONDUCTING THE TRIAL AT YOUR HOSPITAL

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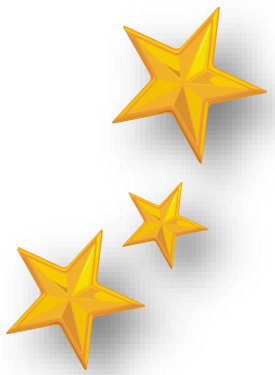
Conducting the trial at your hospital – version 2.0 date 23/07/2017

Making the trial a success

1. Questions to answer before the trial starts
2. Strong trial team
3. Training your trial team
4. Managing the trial at your hospital
5. Ongoing recruitment
6. Celebrate success



Questions to address before the trial starts

- How to create a strong trial team
- How to deal with unhelpful colleagues
- Anxieties about enrolling patients into the trial – do the staff have enough information on the potential risks and benefits?
- Anxieties about explaining the trial to relatives – remember that hospitals interested in research are also at the forefront of delivering best available care.
- How to keep randomisation going?
- Remembering to recruit – how will your team remember the trial in a clinical emergency?
- Incentive to recruit – why should your team take on additional trial related work?

Getting your colleagues to support the trial

- **Create a strong HALT-IT team:** members should be fully informed and enthusiastic about the trial so they can talk about it to others. There are plenty of training materials available – please ensure your team has access to them.
- **Spread the word:** talk about the trial with your colleagues – ideally before it starts – so that as many people as possible know your hospital is participating.
- **Promotion:** the trial will be most successful if supported by all relevant departments. Every specialty should be represented in your team.

How to create a strong HALT-IT trial team

- Identify colleagues who are involved in the care of GI bleeding patients, including Emergency Medicine, Gastroenterology, ITU, medicine, surgery
- Identify who will help you with identification of eligible patients, randomisation, treatment, consent procedures, follow-up, etc.
- Provide information about the trial to all
- Explain every team member's role and its importance for the success of the trial

THE TRIAL BELONGS TO ALL COLLABORATORS.
SUCCESS DEPENDS ON EVERY PERSON
IN YOUR TEAM.

Alleviating concerns about randomising patients

- The trial has been approved by relevant ethics committees
- It will be easier for your team members to carry out the procedures if they are fully trained
- Training materials can be found in the Study File and on the trial website
- ICH-Good Clinical Practice guidelines and the Declaration of Helsinki both support the randomisation of patients in a clinical emergency without prior written consent as long as the procedures set out in the trial protocol are followed

TRAINING FILMS FOR YOUR TEAM:

HOW TO DO THE TRIAL: Walk through the consent process and randomising a patient into the trial, drug administration, data collection, and study file maintenance

SCIENTIFIC RATIONALE: The scientific case and rationale explained

Remember: the team at the Coordinating Centre are always available to answer questions

Alleviating concerns about randomising patients

MANUAL OF OPERATING PROCEDURES (MOP)

- Overview of the trial processes for principal investigators, sub-investigators, doctors, nurses, national coordinators, pharmacists, monitors, other people with responsibilities in the trial
- Important that all personnel involved are familiar with the sections relevant to their duties
- PI needs to be familiar with the complete MOP

GOOD CLINICAL PRACTICE (GCP) TRAINING

- All team members should be GCP trained
- See presentation titled 'GCP test guidance'

How to ensure ongoing recruitment

HOLD REGULAR TEAM MEETINGS AND ENSURE THE HALT-IT TRIAL IS ON THE AGENDA

Things to discuss:

- Current status of the trial: Ensure all team members are aware of the current status i.e. how many patients recruited worldwide / at your hospital
- Recruitment strategies: Eligible patients missed at certain times of the day – can this be improved? Personal experiences of the trial → resolution of any problems
- Motivation: Encouragement – keep team motivated
- Training: Train new staff – refresh team members on trial procedures
- Collaboration: This is a collaborative effort and will be most successful if everyone works together

The PI should arrange holiday cover if they are planning to be away from the unit so that randomisation into the trial can continue in their absence.

Managing the trial at your hospital

Ensure your whole team knows:

- who is responsible if PI is not there; identify key people; let TCC know who to contact
- where drug boxes are stored
- which drug box is currently in use
- how the PI will know when patients are randomised
- who is responsible for ensuring data forms completed
- who is responsible for sending data

Managing the trial at your hospital

Ensure your whole team knows:

- how to assess eligibility
- consent procedures, including waiver and who can give consent on the patient's behalf
- how data should be sent
- where investigator study file is kept and who is responsible for maintaining it

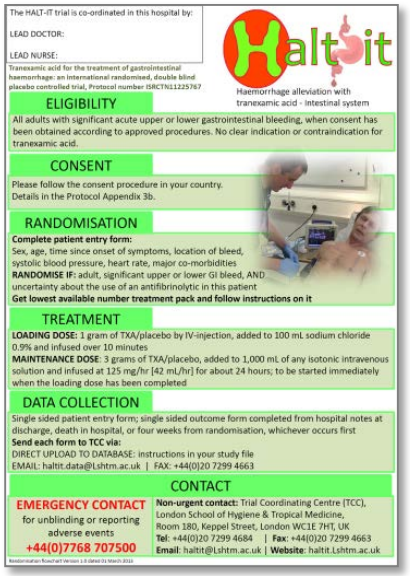
- what to do if trial materials run out
- what to do if team members need advice about the trial
- what to do if there is an adverse event

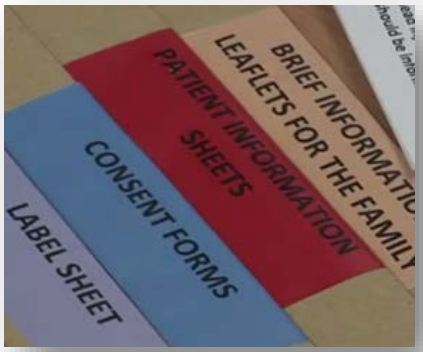
Remembering the trial in a clinical emergency

- **Pocket cards:** ensure all team members have a pocket card with trial instructions which they can carry with them at all times.
- Let the TCC know if you need any **personalised materials** to help your team.
- **Reminders:** advertise the trial at relevant hospital departments using the wall posters provided.
- **Contact** with the trial coordinating team; send mobile numbers and email addresses of the team to TCC – we will help remind them.

Remembering the trial in a clinical emergency

- **Posters:** the trial should be advertised in all relevant hospital departments
- Place posters in strategic places so randomising doctors do not miss eligible patients
- Extra posters available if needed
- Posters available in your local language or in varying sizes – please contact the TCC





Celebrate successes

- **Feedback:** all team members should receive feedback about their contribution to the trial.
- **Praise:** all team members should be congratulated for their hard work.
- **Incentives:** TCC can provide incentives and certificates. Please share these between the team members.
- Please provide the TCC with names, email addresses and phone numbers of all team members – **we would like to thank them personally**.
- The TCC regularly features hospital teams in the trial **newsletter and the website**. Send us a photo of your team and let us know of any trial related news or other achievements that we might like to mention.

JOIN THE GLOBAL COLLABORATION

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