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Transfusion in Gastrointestinal Bleeding (TRIGGER)

Submission date	Recruitment status	[X] Prospectively registered
25/07/2012	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
26/07/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
29/08/2019	Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT02105532

Protocol serial number
12078

Study information

Scientific Title

A multi-centre, feasibility, cluster randomised controlled trial comparing restrictive versus liberal blood transfusion strategies in adult patients admitted with acute upper gastrointestinal bleeding.

Acronym
TRIGGER

Study objectives
Acute upper gastrointestinal bleeding (AUGIB) accounts for 14% of all red blood cell (RBC) transfusions in England. In 2007, a large UK national audit of AUGIB highlighted areas of variation and uncertainty in RBC transfusion practice together with signals of harm associated with more liberal use of RBCs, justifying the need for a randomised controlled trial (RCT) to answer a key area of clinical uncertainty.
TRIGGER is a pragmatic cluster randomised feasibility trial aiming to recruit adult patients admitted to hospital with all cause AUGIB. The study will take place in six UK hospitals and each hospital will be randomised to a transfusion policy; three sites will be randomised to a restrictive transfusion policy and three to a liberal transfusion policy. Both transfusion policies are used by doctors and hospitals in the UK already as part of routine care in the management of AUGIB and are within the limits of local hospital, national and international guidelines. Each cluster will agree to follow the transfusion policy for all eligible patients admitted with AUGIB for a total of 6 months at each site. Consent will be sought from an appropriate "guardian" of the cluster and individual participants for use of data collection and Day 28 telephone follow up. Given the challenges involved in early recruitment and cross-specialty care of patients, a feasibility study is essential to both justify and inform the design of a phase III trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC 20/04/2012, ref: 12/SC/0062

Primary study design
Interventional

Study design
Randomised interventional pilot study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Non-malignant haematology

Interventions
Transfusion Policies:
The trial will compare two different policies for RBC transfusion, 'restrictive' and 'liberal'.

Restrictive transfusion policy: Patients in hospitals allocated to this group will receive a transfusion if their Hb level is =8 g/dL. The objective for the attending clinician is then to maintain the Hb level between 8.1-10 g/dL
Liberal transfusion policy: Patients in hospitals allocated to this group will receive a transfusion

if their Hb level is =10 g/dL.
The objective for the attending cl; Follow Up Length: 1 month(s)

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome(s)
1. Protocol adherence
2. Selection bias
3. Recruitment rate
4. Red cell exposure
5. Information to inform the sample size of the phase III trial

Clinical Outcomes: Further bleeding up to Day 28: Further bleeding is a composite outcome that includes persistent bleeding

Key secondary outcome(s)
1. Further bleeding
2. 28-day mortality
3. Infections
4. Ischaemic/thromboembolic events

We will also collect data to guide a Health Economic evaluation for the phase III trial.

Completion date
01/02/2013

Eligibility

Key inclusion criteria
1. Adults aged = 18 years presenting with AUGIB, defined by haematemesis or melaena.
2. >20 admissions with AUGIB per month
3. >400 hospital beds
4. Availability of 24 hours endoscopy and on-site access to intensive care and surgical support
5. Institutional agreement to transfuse all eligible new admissions with AUGIB in accordance with the randomised transfusion policy
6. Male & female participants
7. Lower Age Limit 18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Patients for whom the responsible clinician considers there is a need for immediate RBC transfusion prior to obtaining or regardless of the initial Haemoglobin (Hb) result due to severity of bleeding (these patients should be managed according to the hospital's massive transfusion protocol or clinician discretion)
2. Existing hospital inpatients who develop an AUGIB

Date of first enrolment
01/09/2012

Date of final enrolment
01/02/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
John Radcliffe Hospital
Oxford
United Kingdom
OX3 9BQ

Sponsor information

Organisation
NHS Blood and Transplant Research & Development (UK)

ROR
https://ror.org/0227qpa16

Funder(s)

Funder type

Research organisation

Funder Name
NHS Blood and Transplant [NHSBT] (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	29/04/2015		Yes	No
Results article	results	11/07/2015		Yes	No
Protocol article	protocol	01/07/2013		Yes	No
Other publications	strategies	21/11/2014		Yes	No
Statistical Analysis Plan	statistical analysis plan	10/07/2013		No	No