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Restrictive and Liberal Transfusion Strategies in Intensive Care (RELIEVE)

Submission date 24/11/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 03/12/2009	**Overall study status** Completed	
Last Edited 12/12/2013	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.clinicaltrials.ed.ac.uk/trials/relieve

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00944112

Secondary identifying numbers
CZB/4/698; UKCRN ID 6606

Study information

Scientific Title
A feasibility randomised trial comparing restrictive and liberal blood transfusion strategies in patients requiring four or more days in intensive care (ICU)

Acronym
RELIEVE

Study objectives
The most effective transfusion practice in critically ill ICU patients is unknown. Currently the data is unclear as to whether a liberal or restrictive transfusion policy is of most benefit to patients in the short and longer term.
The aim of this study is to test the hypothesis that liberal use of red blood cells (RBCs) (Hb transfusion trigger less than or equal to 90g/L; target Hb range 91-110 g/L) to correct anaemia improves clinical outcomes compared with a restrictive transfusion trigger (Hb transfusion trigger less than or equal to 70 g/L; target Hb range 71-90 g/L) in anaemic critically ill patients requiring prolonged ICU stay (4 days or more).

Further reading:
1. http://www.ncbi.nlm.nih.gov//pubmed/18679112
2. http://www.ncbi.nlm.nih.gov//pubmed/9971864
3. http://www.ncbi.nlm.nih.gov//pubmed/16328221
4. http://www.ncbi.nlm.nih.gov//pubmed/12076437

For further information, please visit www.eccrg.org.uk

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Primary ethics approval received from the Scotland A Research Ethics Committee on the 8th of May 2009 (ref: 09/MRE00/24)
2. English ethics approval received from the Leeds (West) Research Ethics Committee on the 17th of August 2009 (ref: 09/H1307/66)

Study design
Multicentre single blind randomised controlled feasibility study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
http://www.clinicaltrials.ed.ac.uk/trials/relieve/resources/Patient_Information_Sheet_(Scotland).pdf

Health condition(s) or problem(s) studied
Anaemia; Blood Transfusion; Intensive Care

Interventions
Added to record on 29th November 2010. Follow-up completed, study now closed.

Added to record 21/06/2010: Recruitment completed on 5th May 2010, study currently in follow-up phase.

Participants will be randomised to one of two treatment arms; restrictive or liberal. Outcome measures of the two groups will be compared.

Restrictive RBC Transfusion
Patients will receive single unit RBC transfusions with a transfusion trigger of 70 g/L or less with a target Hb concentration of 71-90 g/L during the intervention period.

Liberal RBC Transfusion
Patients will receive single unit RBC transfusions with a transfusion trigger of 90 g/L or less with a target Hb concentration of 91-110 g/L during the intervention period.

The intervention period in both treatment arms will last a minimum of 14 days or until discharge from the intensive care unit, whichever is longer. Participants will be followed up for a 6 month period from the date of randomisation.

Joint Sponsor Details
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Study Centres
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London

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Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Primary outcomes are related to feasibility and include recruitment rate, protocol adherence & difference in mean Hb concentration and RBC exposure between the 2 groups.
Data will be collected from the medical records at the end of the intervention period or at 60 days.

Secondary outcome measures
1. Assessment of the complication rate in the two treatment arms: data on the following will be collected from medical records at 60 days.
1.1. organ failures
1.2. acute coronary syndromes
1.3. thromboembolic and cerebrovascular events
1.4. number of ventilation and antimicrobial free days
2. Assessment of length of stay in ICU and hospital. Data collected from medical records.
3. Long term follow-up to determine survival status and assess mobility, quality of life & use of health services. Data collected using the following questionnaires which will be sent at 2 and 6 months.
3.1. Rivermead Mobility Index
3.2. Quality of Life questionnaire (SF12v2)
3.3. Health Economic questionnaire (6 month follow-up only)

Overall study start date
01/08/2009

Completion date
01/11/2010

Eligibility

Key inclusion criteria
1. The patient remains in the ICU after 96 hours (4 days) or more following ICU admission
2. The patient has required mechanical ventilation via an endotracheal tube or tracheostomy tube for 96 hours or more
3. The patient is expected to require 24 hours or more of further mechanical ventilation at the time of assessment
4. The patient is aged 55 years of age or older
5. The patient has a Hb value of 90g/L or less at the time of assessment

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Patient with active bleeding at the time of screening
2. Patient with traumatic brain injury as presenting diagnosis
3. Patient with intracranial haemorrhage as presenting diagnosis
4. Patient not expected to survive the next 48 hours at the time of assessment.
5. Patient objects to RBC transfusion
6. Patient receiving concurrent treatment with erythropoietin or similar erythropoietic agent
7. Follow up is not feasible
8. Already enrolled in another RCT with similar clinical endpoints

Date of first enrolment
01/08/2009

Date of final enrolment
01/11/2010

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
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Sponsor type
University/education

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http://www.ed.ac.uk

ROR
https://ror.org/01nrxwf90

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office (UK) (ref: CZB/4/698)

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location

United Kingdom

Funder Name
Additional support has been provided by the Transfusion Medicine Education and Research Foundation (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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	01/10/2013		Yes	No