

Restrictive and Liberal Transfusion Strategies in Intensive Care (RELIEVE)

Submission date 24/11/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/12/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/12/2013	Condition category Surgery	<input type="checkbox"/> Individual participant data

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)
NCT00944112

Protocol serial number
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

Study type(s)

Treatment

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

Chief Investigator: Prof. Timothy S Walsh
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Principal Investigator: Dr Stephen Cole
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Dundee

Principal Investigator: Dr Rupert Pearse
The Royal London Hospital
London

Principal Investigator: Dr Duncan Wyncoll
St Thomas' Hospital
London

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome(s)

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.

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Other

Sex

All

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**

United Kingdom

Scotland

Study participating centre**Intensive Care Unit**

Edinburgh

United Kingdom

EH16 2SA

Sponsor information**Organisation**

University of Edinburgh (UK)

ROR

<https://ror.org/01nrxf90>

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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes