

A small pilot feasibility study for a possible randomised control trial comparing clinical outcomes and quality of life following two different transfusion strategies in children undergoing allogeneic hematopoietic stem cell transplant (HSCT)

Submission date 20/05/2019	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/05/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 01/08/2025	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

This is a small pilot feasibility study for a possible randomised controlled trial comparing clinical outcomes and quality of life following two different transfusion strategies in children undergoing allogeneic hematopoietic stem cell transplant (HSCT). Children who undergo allogeneic HSCT usually receive red blood cell transfusions in the initial period after their transplant, due to reduced haemoglobin levels as a result of bone marrow suppression. In this situation, the red cell transfusions are commonly given when the child's haemoglobin falls below 70-80g/L. The evidence for this practice is based largely on clinical trials which suggest that in most situations transfusing red cells at haemoglobin thresholds of 70g/L is sufficient, with no benefit of transfusing at higher haemoglobin thresholds. However, this evidence is largely from adult trials in non-HSCT patients. Clinical studies are required to help us understand the best strategy for use of red cell transfusions in paediatric HSCT.

Who can participate?

Patients aged between and including 1 and 17 years who are due to undergo allogeneic Haematopoietic Stem Cell Transplant and are expected to require red cell transfusions can participate.

What does the study involve?

Patients aged between and including 1 and 17 years will participate in this study for the first 100 days after their transplant. Patients will be randomised between the two red cell transfusion strategies: transfusing at a haemoglobin threshold of ≤ 65 g/L (Arm A) or ≤ 80 g/L (Arm B).

Participants of 8 years and older will be asked to fill in short questionnaires about their quality of life at certain intervals during the period of their study. All parents will be asked to fill in an equivalent parent questionnaire

What are the possible benefits and risks of participating?

Benefits: Patients in Arm B (higher haemoglobin threshold) may receive a few additional transfusions than they would have had if they had not participated in the trial and patients in Arm A (lower haemoglobin threshold) may receive slightly fewer transfusions.

Risks: As for all blood transfusions, there are small risks associated with having a transfusion. These risks are described in the national transfusion leaflets produced by NHS Blood and Transplant and SNBTS. This includes the very small risks of catching an infection, such as hepatitis B or HIV (the virus that causes AIDS). Other risks include allergic reactions or developing antibodies to the blood transfused. However, all the paediatric patients undergoing allogeneic HSCT participating in the trial will be expected to receive red cell transfusions and are likely to have had multiple transfusions previously, and so these are not new risks for them. NHSBT has a rigorous system for testing all blood donations for viruses such as hepatitis B or HIV.

Where is the study run from?

NHSBT Clinical Trials Unit, Cambridge, UK.

When is the study starting and how long is it expected to run for?

June 2019 to June 2023

Who is funding the study?

NHS Blood and Transplant, UK

Who is the main contact?

CTU@nhsbt.nhs.uk

Contact information

Type(s)

Scientific

Contact name

Dr NHS Blood and Transplant (NHSBT) Clinical Trials Unit (CTU)

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

246398

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

CPMS 41935

Study information

Scientific Title

Red Cell Transfusion in Paediatric Allogeneic HSCT

Acronym

RePAST

Study objectives

The principal research question is to see if it is feasible to recruit and achieve adherence to a transfusion protocol when randomising patients to one of two haemoglobin thresholds. The study will be considered feasible and worthy of further development into a larger randomised trial if at least half of eligible patients are randomised, and if there is no evidence that the adherence to the protocol (such that transfusions are given appropriately in accordance with the randomised haemoglobin threshold policy) is lower than 70% in either arm. The results will help design a larger multi-centre randomised, controlled trial to be conducted in the future, or may show that it is not possible to carry out such a trial.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 24/06/2019, London – Camden and King's Cross REC (Friends House, Margaret Fell Room, 173 - 177 Euston Road, London, NW1 2BJ, United Kingdom; +44 (0)2071048238; camdenandkingscross.rec@hra.nhs.uk), ref: 19/LO/0714

Study design

Interventional; Design type: Process of Care, Management of Care

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Red cell transfusion

Interventions

This is a small pilot feasibility study for a possible randomised controlled trial comparing clinical outcomes and quality of life following two different transfusion strategies in children undergoing allogeneic hematopoietic stem cell transplant (HSCT).

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Patients aged between and including 1 and 17 years will participate in this study for the first 100 days after their transplant. Patients will be randomised between the two red cell transfusion strategies: transfusing at a haemoglobin threshold of ≤ 65 g/L (Arm A) or ≤ 80 g/L (Arm B).

Participants of 8 years and older will be asked to fill in short questionnaires about their quality of life at certain intervals during the period of their study. All parents will be asked to fill in an equivalent parent questionnaire.

Intervention Type

Other

Primary outcome(s)

Current primary outcome measures as of 20/01/2025:

Recruitment: The percentage of eligible children recruited and randomised into the study

Adherence: The percentage of Hb measurements where appropriate action was taken in accordance with the randomised policy

Previous primary outcome measures:

Adherence outcomes:

1. The proportion of enrolled participants for whom the transfusion policy was successfully followed
2. The proportion of red cell transfusions given in accordance with the randomisation policy where the correct dose was given
3. The mean pre-transfusion, post-transfusion and overall haemoglobin concentration (g/L) up to day 100 of HSCT and the difference between the two arms
4. The percentage of pre-transfusion haemoglobin concentrations falling at or below, or above the threshold haemoglobin of the red cell transfusion threshold assigned
5. The percentage of post-transfusion haemoglobin concentrations falling below, or at and above the target haemoglobin of the red cell transfusion threshold assigned
6. Drop out: the proportion of randomised participants who were withdrawn from the study
7. Quality of Life (QoL) questionnaire compliance: the proportion of QoL questionnaires completed at each time point

Key secondary outcome(s)

Current secondary outcome measures as of 20/01/2025:

Adherence outcomes:

1. The proportion of enrolled participants for whom the transfusion policy was successfully followed
2. The proportion of RBC transfusions given in accordance with the randomised policy where the correct dose was given
3. The mean pre-transfusion, post-transfusion and overall Hb concentration up to Day 100 of HSCT and the difference between the two arms
4. The percentage of pre-transfusion Hb concentrations falling at or below, or above the threshold Hb of the red cell transfusion threshold assigned
5. The percentage of post-transfusion Hb concentrations falling below, or at and above the target Hb of the red cell transfusion threshold assigned
6. Drop-out: the proportion of randomised participants who were withdrawn from the study
7. Quality of life (QoL) questionnaire compliance: the proportion of QoL questionnaires completed at each time point

Clinical outcomes:

1. Death: All-cause mortality at Day 100 of HSCT
2. Clinically significant bleeding (WHO Grade 3-4)
3. Red Blood Cell Exposure: The RBC transfusion volume per recipient weight (ml/Kg), number of red blood cell units administered and number of RBC transfusion episodes up to death/Day 100 of HSCT (whichever comes first). Number of patients requiring an additional transfusion within 24 hours, and reason
4. Proportion of participants experiencing thromboembolic and ischaemic events
5. Transfusion reactions
6. Grade of acute graft versus host disease and Bearman toxicity score
7. Veno-occlusive disease
8. Admission to Paediatric Intensive Care (reason and duration of stay)
9. Number of platelet transfusions
10. Health-related QoL scores

Previous secondary outcome measures:

Clinical outcomes:

1. Death: all-cause mortality at Day 100 of HSCT
2. Clinically significant bleeding (WHO Grade 3-4)
3. Red cell exposure: the red cell transfusion volume per recipient weight (ml/Kg), number of red cell units administered and number of red cell transfusion episodes up to death/Day 100 of

HSCT (whichever comes first)

4. Number of patients requiring an additional transfusion within 24 hours, and reason

5. Proportion of participants experiencing thromboembolic and ischaemic events

6. Transfusion reactions

7. Grade of acute graft versus host disease and Bearman toxicity score

8. Veno-occlusive disease

9. Admission to Paediatric Intensive Care (reason and duration of stay)

10. Number of platelet transfusions

11. Health-related Quality of Life Scores.

Completion date

30/06/2023

Eligibility

Key inclusion criteria

1. Children undergoing allogeneic HSCT

2. Aged at least 1 year and under 18 years at time of consent

3. Expected to require red cell transfusions

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

1 years

Upper age limit

18 years

Sex

All

Total final enrolment

34

Key exclusion criteria

1. Patients for whom the attending haematologist feels allocation to either a restrictive or liberal policy of red cell transfusion is not appropriate (e.g. acutely unwell, bleeding or 'unstable').

2. Children undergoing HSCT for haemoglobinopathy or red cell aplasia.

Date of first enrolment

01/06/2019

Date of final enrolment

01/12/2020

Locations

Countries of recruitment

United Kingdom

England

Scotland

Study participating centre

University Hospitals Bristol NHS Foundation Trust

Marlborough Street

Bristol

United Kingdom

BS1 3NU

Study participating centre

NHS Greater Glasgow and Clyde

J B Russell House

Gartnavel Royal Hospital

1055 Great Western Road

Glasgow

United Kingdom

G12 0XH

Study participating centre

Sheffield Childrens Hospital

Western Bank

Sheffield

United Kingdom

S10 2TH

Study participating centre

Manchester University NHS Foundation Trust

Cobbett House

Oxford Road

Manchester

United Kingdom

M13 9WL

Sponsor information

Organisation

NHS Blood and Transplant

ROR

<https://ror.org/0227qpa16>

Funder(s)

Funder type

Government

Funder Name

NHS Blood and Transplant; Grant Codes: TF070

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from NHSBT Clinical Trials Unit (CTU@nhsbt.nhs.uk).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Participant information sheet	21/04/2025	15/07/2025	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet		11/11/2025	11/11/2025	No	Yes