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Transfusion Alternatives Pre-operatively in Sickle cell disease

Submission date	Recruitment status	[X] Prospectively registered
23/05/2007	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/05/2007	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/04/2012	Haematological Disorders	[ ] Record updated in last year

Plain English summary of protocol
http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=36

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00512577

Protocol serial number
BS02/4/RB31

Study information

Scientific Title

Acronym
TAPS

Study objectives
The trial aims to investigate whether the administration of a blood transfusion preoperatively to patients with sickle cell disease (Hb SS or Hb SB thal) increases or decreases the overall rate of peri-operative complications. The proportions of patients with peri-operative complications in two randomised groups of transfused and untransfused patients will be compared.

Amended as of 12/01/2012
Countries of recruitment: USA was deleted and Netherlands, Canada and Ireland were added.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London Multicentre Research Ethics Committee on 04/12/2006 (ref: 06/MRE02/43).

Study design
A phase III, multicentre, parallel group, group-sequential randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Sickle Cell Disease

Interventions
Patients will be randomised to one of two arms:
Arm A will not receive a pre-operative blood transfusion.
Arm B will receive a pre-operative blood transfusion (top-up or exchange depending on Hb level).

The follow-up period is 30 days post surgery with a blood sample taken additionally at three months post surgery.

As of 17/01/2012, the trial was stopped prematurely because of an excess of SAEs in one or the two arms.

Intervention Type
Other

Phase
Phase III

Primary outcome(s)
The frequency of all clinically significant complications in sickle cell patients (Hb SS or SB thal) undergoing low or medium risk planned surgery between day of randomisation and 30 days post surgery, inclusive.

Key secondary outcome(s))
1. Complications included in the primary outcome, plus red cell alloimmunisation at three months post surgery
2. Total days in hospital up to 30 days post surgery, to include hours/days spent having pre-operative transfusion, days on intensive care and high dependency units, and other wards
3. Re-admission or failure to discharge within 30 days post surgery
4. Number of red cell units received (intra and post-operatively)
5. Health Economic Analysis incorporating the following elements:
5.1. Differential health service costs of routine transfusion relative to control
5.2. Differential benefits of routine transfusion in terms of quality adjusted survival
5.3. The cost-effectiveness of the two forms of management based on differential costs
5.4. Benefits and quality-adjusted life years

Completion date
05/06/2012

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
Current inclusion criteria as of 12/01/2012
1. Patient is one year of age or more
2. Sickle cell disease, either Hb SS or Hb SB thal, confirmed by Hb electrophoresis, deoxyribonucleic acid (DNA) analysis or high performance liquid chromatography (HPLC)
3. At least 24 hours and no more than 28 days before surgery and a date for surgery has been given
4. Surgery to be low or medium risk
5. Surgery to be with general or regional anaesthesia
6. Written informed consent from patient/parent/guardian is given
7. More than six months since previous TAPS trial surgery

Previous inclusion criteria
1. Patient is one year of age or more
2. Sickle cell disease, either Hb SS or Hb SB thal, confirmed by Hb electrophoresis, deoxyribonucleic acid (DNA) analysis or high performance liquid chromatography (HPLC)
3. At least 24 hours and no more than 14 days before surgery and a date for surgery has been given
4. Surgery to be low or medium risk
5. Surgery to be with general or regional anaesthesia
6. Written informed consent from patient/parent/guardian is given
7. More than six months since previous TAPS trial surgery

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Current exclusion criteria as of 12/01/2012
1. Having a procedure involving intravascular contrast radiography or an imaging procedure
2. On a regular blood transfusion regime
3. Had a blood transfusion within the last three months
4. The planned procedure involves local anaesthetic only
5. Haemoglobin level at randomisation less than 6.5 g/dL
6. Children with a clinical history of stroke (history of silent infarcts would not preclude randomisation)
7. Acute chest syndrome within the last six months, or patient has ever required intubation and mechanical ventilation for treatment of acute chest syndrome which is still relevant to their condition.
8. Oxygen saturation at randomisation less than 90%
9. Patient is on renal dialysis
10. Already entered twice into the TAPS trial
11. The physician is unwilling to randomise the patient (such patients will be entered into a trial log)

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Date of first enrolment
05/06/2007

Date of final enrolment
05/06/2012

Locations

Countries of recruitment
United Kingdom

England

Canada

Ireland

Netherlands

Study participating centre
National Blood Service
Cambridge
United Kingdom
CB2 2PT

Sponsor information

Organisation
NHS Blood and Transplant (NHSBT) (UK)

ROR
https://ror.org/0227qpa16

Funder(s)

Funder type
Government

Funder Name
The National Blood Service (UK) (ref: BS02/4/RB31) - an operating division of NHS Blood and Transplant: project grant

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?

Study website	Study website	11/11/2025	11/11/2025	No	Yes