

Transfusion Alternatives Pre-operatively in Sick cell disease

Submission date 23/05/2007	Recruitment status Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/05/2007	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 18/04/2012	Condition category Haematological Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=36

Study website

<http://www.ctu.mrc.ac.uk/studies/taps.asp>

Contact information

Type(s)

Scientific

Contact name

Dr Lorna Williamson

Contact details

National Blood Service
Long Road
Cambridge
United Kingdom
CB2 2PT

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00512577

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

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.

Secondary outcome measures

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

Overall study start date

05/06/2007

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. Sick 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

Age group

Not Specified

Sex

Not Specified

Target number of participants

As this is a sequential trial the exact number cannot be anticipated but it is predicted that approximately 400 patients will be recruited to the study.

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

Canada

England

Ireland

Netherlands

United Kingdom

Study participating centre**National Blood Service**

Cambridge

United Kingdom

CB2 2PT

Sponsor information

Organisation

NHS Blood and Transplant (NHSBT) (UK)

Sponsor details

Professor Marion Scott

Bristol Institute of Transfusion Services

Southmead Road

Bristol
United Kingdom
BS10 5ND

Sponsor type
Government

Website
<http://www.nhsbt.nhs.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

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