Transfusion Alternatives Pre-operatively in Sickle Cell Disease (TAPS study) Randomised Controlled Trial

Published: 17-11-2009
Last updated: 04-05-2024

To study whether preoperative transfusion increases or decreases the likelihood of having problems after surgery

Ethical review	Approved WMO
Status	Pending
Health condition type	Haemoglobinopathies
Study type	Interventional

Summary

ID

NL-OMON33426

Source
ToetsingOnline

Brief title
TAPS study

Condition

- Haemoglobinopathies

Synonym
sickle cell anemia, sickle cell disease

Research involving
Human

Sponsors and support

Primary sponsor: NHS BLood Transplant, Bristol Institute for Transfusion Services
Source(s) of monetary or material Support: National Health Service Blood and Transplant;United Kindom

Intervention

Keyword: Pre-operative, Sickle Cell Disease, Surgical, Transfusion

Outcome measures

Primary outcome

The primary outcome measure is the frequency of all clinically significant

complications (sickle

related, transfusion related, surgical and infections) between the day of

randomisation and up

to and including 30 days post surgery.

Secondary outcome

Secondary outcome measures will include:

complications included in the primary outcome plus red cell alloimmunisation at

3 months, total

hospital days including ICU (pre, intra and post-operative), number of red cell

units received

intra and post-operatively, readmission or failure to discharge up to and

including the 30th day

following surgery.

Study description

Background summary

Patients with sickle cell disease (SCD) often have a blood transfusion before they have surgery. This is done in the belief that it reduces the risk of having sickle cell related problems after surgery. On the other hand, blood transfusion itself may carry some risks. In particular, it may decrease the

body's ability to fight the types of infection which sometimes happen after surgery eg chest or wound infections. Not all patients receive a blood transfusion before surgery however, and some reports suggest that these patients do equally well. Unfortunately there haven t been many studies looking into this, so it isn t really known if blood transfusion helps or not. We are carrying out a study, known as a randomised controlled trial (RCT), to find out whether there is really a need to give blood transfusions before surgery to people with SCD. Patients will be randomly put into two equal groups before planned surgery; one group will have a transfusion and the other group will not. . Approximately 400 patients will be needed to take part in the study in order to discover which is the best treatment for sickle cell patients before surgery.

Study objective

To study whether preoperative transfusion increases or decreases the likelihood of having problems after surgery

Study design

A multicentre, pragmatic, parallel group, group sequential (3), randomised controlled trial. Because of the nature of the intervention, the trial will not be blinded.

Intervention

Pre-operative transfusion.

Study burden and risks

not applicable

Contacts

Public
NHS BLood Transplant, Bristol Institute for Transfusion Services

Bristol
BS10 5ND
GB
Scientific
NHS BLood Transplant, Bristol Institute for Transfusion Services

Bristol

BS10 5ND
GB

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Patient inclusion criteria;1. Patient is one year of age or older
2. Sickle cell disease, either HbSS or HbSBeta0-thal, confirmed by Hb electropheresis, DNA analysis or 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 (see below and Appendix F)*
5. Surgery to be with general or regional anaesthesia.
6. Written informed consent from patient/parent/guardian is given
7. More than 6 months since previous TAPS trial surgery**

Exclusion criteria

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 <6.5g/dL (4 mmol/l).
6. Children with a clinical history of stroke (history of silent infarcts would not preclude randomisation).
7. Acute chest syndrome within the last 6 months, or patient has ever required

intubation and mechanical ventilation for treatment of acute chest syndrome.
8. 0xygen saturation at randomisation <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).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2009
Enrollment:	50
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ISRCTN	ISRCTNNumber:00862331
CCMO	NL28295.018.09