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Umbilical cord blood transfusion for children with severe anaemia (Wazo Geni study)

Submission date	Recruitment status	[_] Prospectively registered
01/07/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/07/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
22/12/2015	Haematological Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SSC 1215

Study information

Scientific Title
An unmasked, single arm trial to assess harm, safety and efficacy of umbilical cord red blood cell transfusion for children with severe anaemia in a Kenyan hospital

Study objectives
Please note that as of 16/02/2009 this record was updated to include an amendment of the protocol from packed cord red blood cell transfusion to umbilical cord blood transfusion. All updates can be found in the relevant field under the above update date. The initial title (one title only) at the time of registration was: 'The safety and efficacy of packed cord red blood cell transfusion in children with severe anaemia in a Kenyan hospital'. Please also note that the anticipated end date has also changed; the initial end date at the time of registration was 31/03 /2008.

Current hypothesis as of 16/02/2009:
Transfusion of umbilical cord red blood cells is safe and efficacious in the management of children with severe anaemia requiring blood transfusion in a Kenyan hospital.

Initial information at time of registration:
Transfusion of packed cord red blood cells is safe and efficacious in the management of children with severe anaemia requiring blood transfusion in a Kenyan hospital.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from:
1. KEMRI/National Ethics Committee on the 6th June 2007 (ref: SSC 1215)
2. Liverpool School of Tropical Medicine Research Ethics Committee on the 18th April 2007 (ref: 07.15)

Study design
Phase 1b, open-label, non-randomised, non-controlled, single arm trial

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Severe anaemia

Interventions
Amended as of 16/02/2009:
Umbilical cord red blood cells from a maximum of two cord blood donations to provide a minimum quantity of haemoglobin equivalent to 20 ml/kg of adult-donated whole blood. Transfusions will be over 3 - 4 hours, with or without frusemide according to current international guidelines.

There will be one transfusion episode per child. If further transfusions are required the child will receive standard management. Follow-up is for 28 days.

Initial information at time of registration:
A volume of packed cord blood cells from up to two cord blood units to be transfused to provide a minimum quantity of haemoglobin equivalent to 20 ml/kg of adult-donated whole blood. Transfusions will be over 3 - 4 hours, with or without frusemide according to current international guidelines.

There will be one transfusion episode per child. If further transfusions are required the child will receive standard management. Follow-up is for 28 days.

Intervention Type
Drug

Phase
Phase I/II

Drug/device/biological/vaccine name(s)
Umbilical cord blood transfusion

Primary outcome measure
Amended as of 16/02/2009:
1. Serious adverse events
2. Suspected unexpected serious adverse reactions
3. Adverse events

Initial information at time of registration:
1. Serious adverse events
2. Suspected unexpected serious adverse reactions

Monitored throughout in-patient stay with formal assessments at the following times:
1. Pre-transfusion
2. During transfusion
3. Two hours post transfusion
4. 24 hours post transfusion
5. At hospital discharge
6. 28 days post transfusion

Secondary outcome measures
Rise in haemoglobin at 24 hours and 28 days.

Overall study start date
25/06/2007

Completion date
17/06/2008

Eligibility

Key inclusion criteria
1. Children aged 12 years or less, either sex
2. Children with severe anaemia for whom a blood transfusion is indicated (aged less than three months, Haemoglobin [Hb] less than or equal to 10 g/dL; aged greater than three months, Hb less than or equal to 4 g/dL)

Participant type(s)
Patient

Age group
Child

Upper age limit
12 Years

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Coma (Blantyre Coma Scale less than or equal to 2)
2. Prostration (if unable to sit when well, inability to take enteral feeds; if able to sit when well, inability to sit unsupported)
3. Uncompensated shock
4. Compensated shock (capillary refill time greater than 3 seconds; temperature gradient)
5. Respiratory distress (deep breathing)
6. Neonatal hyperbilirubinaemia requiring exchange transfusion
7. Any other marker of clinical severity considered to preclude the child from recruitment into the study
8. Enrolment in another intervention trial
9. Children for whom informed consent to enter the study is not possible or not given

Date of first enrolment
25/06/2007

Date of final enrolment
17/06/2008

Locations

Countries of recruitment
Kenya

Study participating centre
KEMRI/Wellcome Trust Research Laboratories
Kilifi
Kenya
80108

Sponsor information

Organisation
Liverpool School of Tropical Medicine (UK)

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Sponsor type
University/education

Website
http://www.liv.ac.uk/lstm/

ROR
https://ror.org/03svjbs84

Funder(s)

Funder type
Charity

Funder Name
The Wellcome Trust (UK) - Training Fellowship (grant ref: 073604)

Results and Publications

Publication and dissemination plan
Publication in 2015.

Intention to publish date
01/07/2015

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	01/03/2015		Yes	No