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The use of albumin to prevent exchange blood transfusions and improve outcome in neonates with severe hyperbilirubinaemia

Submission date	Recruitment status	[_] Prospectively registered
13/04/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/04/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/09/2019	Neonatal Diseases	

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
KEMRI SCC 1016

Study information

Scientific Title
The use of albumin to prevent exchange blood transfusions and improve outcome in neonates with severe hyperbilirubinaemia

Study objectives
1. To determine if albumin can prevent exchange blood transfusions in neonates with severe hyperbilirubinaemia
2. To determine if albumin improves the outcome of neonates with severe hyperbilirubinaemia

Ethics approval required
Old ethics approval format

Ethics approval(s)
Reviewed and approved by the Kenyan Nathional Ethics Review Committee on the 22nd Mwrch 2006 (ref: KEMRI SCC Protocol No 1016).

Study design
Randomised controlled trial of 20% albumin versus normal maintence fluids in neonates with severe hyperbilirubinaemia (total plasma bilirubin greater than 250 µmols/l).

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
Neonates with severe hyperbilirubinaemia

Interventions
The intervention is 20% Albumin which is compared to normal maintenance fluid. The study participants are randomised into two arms namely those who receive the study drug(20% neonatal albumin in the first two hours) and those who just get routine internationally accepted management for jaundice from the start. After the first two hours the rest of the clinical management is the same. All the children are managed in the ward at the discretion of clinically qualified staff till discharge, thus the inpatient period will vary according to the severity of jaundice and any other co-morbidity.

At discharge general and neurological assessment is done by discharging clinicians for each child and then the discharge Event Related Potentials (ERPs) are performed. After discharge the

children return to routine health care system. In case of any severe illness requiring hospitalisation the study team is informed.

Follow up assessments are planned at 12, 24, 36 months of age. These assessments consist of a general exam with anthropometric measurement and neurodevelopmental exam. Also at each point of exam after discharge, age and sex matched control (who never had jaundice or any severe illness that may lead to neurological impairment) will be used for comparison.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Albumin

Primary outcome measure
1. Number of exchange blood transfusions
2. Mortality

Children will be discharged from the study after the 36 months of age.

Secondary outcome measures
1. Neurological sequelae on discharge and at 12, 24 & 36 months of age.

Children will be discharged from the study after the 36 months of age.

Overall study start date
01/06/2006

Completion date
30/05/2008

Eligibility

Key inclusion criteria
1. Age 0 to 30 days
2. Bilirubin levels greater than 250 µmols/l
3. Neonates whose guardians consent to the study

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
62

Total final enrolment
118

Key exclusion criteria
1. Neonates with gross congenital abnormalities not compatible with life, such as neural tube defects
2. Clinical evidence of kernicterus
3. Severely ill neonates likely to die e.g., neonates with severe respiratory distress
4. Suspected obstructive jaundice e.g., biliary atresia

Date of first enrolment
01/06/2006

Date of final enrolment
30/05/2008

Locations

Countries of recruitment
Kenya

Study participating centre
PO Box 480
Kilifi
Kenya
80108

Sponsor information

Organisation
Kenya Medical Research Institute (KEMRI) (Kenya)

Sponsor details
PO Box 480
Kilifi
Kenya
80108

Sponsor type
Research organisation

Website

http://www.kemri.org/

ROR
https://ror.org/04r1cxt79

Funder(s)

Funder type
Charity

Funder Name
Kenya Medical Research Institute (KEMRI) (Kenya)

Funder Name
Wellcome Trust (grant ref: 077092)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/09/2019	27/09/2019	Yes	No