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

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

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

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Study information

Scientific Title

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

Study objectives

 To determine if albumin can prevent exchange blood transfusions in neonates with severe hyperbilirubinaemia
 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

Number of exchange blood transfusions
 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
Results	article

Details Date created results 23/09/2019 Date added 27/09/2019

Peer reviewed? Yes Patient-facing?

No