

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 registered ☐ Protocol
Registration date 16/04/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 27/09/2019	Condition category Neonatal Diseases	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Michael Mwaniki

Contact details

PO Box 480

Kilifi

Kenya

80108

-

mmwaniki@kilifi.kemri-wellcome.org

Additional identifiers

Protocol serial number

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 National Ethics Review Committee on the 22nd March 2006 (ref: KEMRI SCC Protocol No 1016).

Study design

Randomised controlled trial of 20% albumin versus normal maintenance fluids in neonates with severe hyperbilirubinaemia (total plasma bilirubin greater than 250 μ mol/l).

Primary study design

Interventional

Study type(s)

Treatment

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(s)

1. Number of exchange blood transfusions
2. Mortality

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

Key secondary outcome(s)

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.

Completion date

30/05/2008

Eligibility

Key inclusion criteria

1. Age 0 to 30 days
2. Bilirubin levels greater than 250 $\mu\text{mol}/\text{l}$
3. Neonates whose guardians consent to the study

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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)

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

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