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The role of hypovolaemia In the acidosis of severe malaria in children

Submission date	Recruitment status	[_] Prospectively registered
22/07/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/07/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/02/2020	Infections and Infestations	

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
062258

Study information

Scientific Title
The role of hypovolaemia In the acidosis of severe malaria in children

Study objectives
1. To establish to what degree hypovolaemia contributes to the clinical spectrum of severe malaria
2. To establish, through intervention studies, whether the acidosis of severe malaria can be corrected by adequate volume replacement
3. To examine the safety and efficacy of adequate volume replacement and determine the optimum intravenous fluid (0.9% saline or 4.5% albumin) to use in children with severe malaria

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

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
Severe malaria

Interventions
Open phase II randomised trial comparing the safety and efficacy of volume expansion with 0.9% saline or human albumin to control in children with severe malaria and moderate acidosis (base deficit of eight to 15) and comparing safety and efficacy of 0.9% saline and human albumin as volume expansion in children with severe malaria complicated by severe acidosis (base deficit of more than 15).

Intervention Type
Other

Phase

Phase II

Primary outcome measure
Percentage reduction in acidosis by eight hours.

Secondary outcome measures
1. Death
2. Severe adverse events
3. Neurological sequalae

Overall study start date
01/05/2001

Completion date
01/10/2002

Eligibility

Key inclusion criteria
1. A clinical feature of severe malaria (prostration, coma or deep breathing) plus P. falciparum
2. A base deficit of more than eight
3. Parental consent

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
53

Total final enrolment
53

Key exclusion criteria
1. Clinical features of oedematous malnutrition
2. Features suggestive of pulmonary oedema (oxygen saturations <90% and bilateral creptitations)
3. Raised intracranial pressure (unequal pupillary reaction to light and/or raised blood pressure concurrent with bradycardia)
3. Refusal of consent

Date of first enrolment
01/05/2001

Date of final enrolment

01/10/2002

Locations

Countries of recruitment
Kenya

Study participating centre
KEMRI
Kilifi
Kenya
-

Sponsor information

Organisation
Imperial College London (UK)

Sponsor details
Level 2, Faculty Building
Clinical Research Office
South Kensington campus
London
England
United Kingdom
SW7 2AZ
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Sponsor type
University/education

Website
http://www3.imperial.ac.uk/

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Charity

Funder Name
The Wellcome Trust (UK) (grant ref: 062258)

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	01/10/2003	14/02/2020	Yes	No