

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

Submission date 22/07/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 22/07/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 14/02/2020	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data

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 sequelae

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

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Sponsor information

Organisation

Imperial College London (UK)

Sponsor details

Level 2, Faculty Building

Clinical Research Office

South Kensington campus

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England

United Kingdom

SW7 2AZ

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clinical.researchoffice@imperial.ac.uk

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