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Fluid Expansion As Supportive Therapy in critically ill African children

Submission date 29/11/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 21/01/2009	**Overall study status** Completed	
Last Edited 17/06/2019	**Condition category** 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

Protocol serial number
MRC ref: G0801439

Study information

Scientific Title
A randomised trial of fluid resuscitation strategies in African children with severe febrile illness and clinical evidence of impaired perfusion

Acronym

FEAST

Study objectives
In hospitals throughout sub-Saharan Africa, mortality from malaria and other severe infections in childhood remains at 15-30%, with over 50% of deaths occurring within 24 hours of admission. Currently, antimalarial and antimicrobial drugs are the mainstay of treatment, with little consideration being given to the use of adjunctive supportive therapies. There is considerable debate about the degree to which intravascular volume depletion (hypovolaemia) contributes to the pathophysiology of malaria and other severe infections, and clinical practice varies widely across the continent. To resolve the continuing uncertainty, this multi-centre randomised clinical trial will evaluate different fluid resuscitation strategies in children presenting to hospital with severe febrile illness and clinical evidence of impaired perfusion, with the intention of generating data of practical value to clinicians working in resource-poor settings in Africa.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Imperial College Research Ethics Committee (UK), approved in August 2008 (ref: ICREC_8_1_1)
2. Kenya Medical Research Institute (KEMRI) National Ethics Review Committee (Kenya), approved in July 2008 (ref: SCC 1355)
3. National Ethics Review Committee, Makarere University (Uganda) approved in April 2008
4. NIMRI Ethics Review Board (Tanzania), approved in September 2008 (ref: 748)

Study design
Open randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Severe illness with shock due to sepsis or severe malaria

Interventions
This is a three-arm randomised open controlled trial comparing two active fluid resuscitation strategies to control (no bolus). 2,880 children will be assigned in a ratio of 1:1:1 to one of the three fluid management arms; 144 with decompennsated shock will be randomised to human albumin solution (HAS) or saline.

Three resuscitation strategies:
1. Immediate volume resuscitation with normal (0.9%) saline
2. Immediate volume expansion with 5% human albumin solution (HAS)
3. No immediate volume expansion (control)

Children will be assessed for neurological deficit at 28 days from date of randomisation. A further assessment will be conducted at six months only in children with a persistent neurological sequelae at 28 days.

Please use the following contact details to request a patient information sheet:
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Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
In-hospital mortality at 48 hours after randomisation.

Key secondary outcome(s)
1. Mortality at 4 weeks after randomisation
2. Mortality or neurological sequelae at 4 weeks after randomisation
3. Neurological sequelae at 4 weeks after randomisation
4. Persistent neurological sequelae at 6 months after randomisation
5. Development of hypotensive shock within 48 hours of randomisation
6. Adverse event within 48 hours of randomisation (pulmonary oedema, intracranial hypertension, severe allergic reaction in those receiving albumin)

Completion date
01/12/2011

Eligibility

Key inclusion criteria
Children (both males and females, age range >60 days and <12 years) with severe illness and clinical evidence of impaired perfusion in whom there is uncertainty as to the benefits of immediate fluid resuscitation and what type of fluid to give.

Severe illness and impaired perfusion defined as follows:

1. Severe illness: one or more of the following:
1.1. Impaired consciousness: prostration or coma
1.2. Respiratory distress

Prostration: inability to sit unsupported, or to breast feed if < 9months
Coma: inability to localise a painful stimulus
Respiratory distress: Deep breathing or increased work of breathing

2. Impaired perfusion: one or more of the following:
2.1. Capillary refill time >2s
2.2. Lower limb temperature gradient

2.3. Weak radial pulse volume
2.4. Severe tachycardia

Severe tachycardia: if <12 months: >180 bpm; 12 months to 5 years: >160 bpm; >5 years: >140 bpm

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
60 days

Upper age limit
12 years

Sex
All

Total final enrolment
3141

Key exclusion criteria
One or more of the following at admission:
1. Severe acute malnutrition
2. Gastroenteritis
3. Conditions where intravascular volume expansion is contraindicated, namely chronic renal failure, pulmonary oedema
4. Non-infectious causes of severe illness: trauma, burns, intoxication
5. Children who have already received volume expansion using an isotonic volume expander during the current illness

Severe malnutrition: visible severe wasting and/or kwashiorkor
Gastroenteritis: >3 watery stools in previous 24 hours
Pulmonary oedema: oxygen saturation <90% on pulse oximetry plus bilateral basal crepitations

Date of first enrolment
15/12/2008

Date of final enrolment
01/12/2011

Locations

Countries of recruitment

Kenya

Tanzania

Uganda

Study participating centre
KEMRI Wellcome Trust Unit
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Sponsor information

Organisation
Imperial College of Science, Technology and Medicine (UK)

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
Medical Research Council (UK) (ref: G0801439)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

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	30/06/2011		Yes	No
Results article	results	14/03/2013		Yes	No
Results article	results	01/07/2019	17/06/2019	Yes	No