

# Fluid Expansion As Supportive Therapy in critically ill African children

<b>Submission date</b> 29/11/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 21/01/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 17/06/2019	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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

**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, Makerere 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 decompensated 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**  
Kilifi  
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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?
<a href="#">Results article</a>	results	30/06/2011		Yes	No
<a href="#">Results article</a>	results	14/03/2013		Yes	No
<a href="#">Results article</a>	results	01/07/2019	17/06/2019	Yes	No