ISRCTN67518332 https://doi.org/10.1186/ISRCTN67518332

Gastroenteritis aggressive versus slow treatment for rehydration

Submission date	Recruitment status	[_] Prospectively registered
31/08/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/09/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
02/07/2019	Digestive System	

Plain English summary of protocol

Background and study aims
Gastroenteritis is a very common cause of diarrhoea and vomiting. It is most likely to be caused by a bacterial or viral stomach infection and is particularly common in young children. In some cases, it can cause severe dehydration, a condition that requires immediate medical treatment. Worldwide, an estimated 2.5 billion cases of acute gastroenteritis causing diarrhoea and vomiting occur every year in children under 5 years. In these children, gastroenteritis is the second biggest cause of death (after acute respiratory illnesses) with the vast majority occurring in low income countries such as sub-Saharan Africa. Current guidance recommends fluids via a drip in any child with severe dehydration requiring urgent rehydration. The World Health Organisation (WHO) rehydration regimen can result in a child being given over two times their circulating volume in a very short space of time (3-6 hours depending on the child's age). These recommendations have never been formally tested in a study. This study is looking at two different treatment regimens for treating children that have severe dehydration as a result of gastroenteritis. It compares the current World Health Organisation (WHO) guidelines with a slower regimen involving rehydration over a period of 8 hours.

Who can participate?
Children aged between 60 days and 12 years admitted to hospital with severe dehydration caused by gastroenteritis.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 are rehydrated according to current WHO guidelines (WHO Plan C). This involves giving the child up to 2 x 10-20ml/kg doses (or boluses) of fluid given as fast as possible and then an additional 100ml/kg over 3-6 hours (depending on age). Children in group 2 are given fluids over 8 hours, without the initial fluid boluses i.e. a total of 100ml/kg. All children, regardless of group, are given the same fluid, Ringers lactate. Each child is then monitored regularly and will have blood tests upon admission to hospital and then again after 8 hours and 24 hours. Ultrasound scans are used to check how dehydrated each child is and each child will also undergo have a series of Bioelectrical impedence analyses (BIA - analysis of body water composition by placing electrodes on the wrist and foot, this does not cause any discomfort to the child). Treatment continues until the child is successfully rehydrated.

What are the possible benefits and risks of participating?
Benefits include close monitoring of all children admitted with severe dehydration caused by gastroenteritis. Risks are those associated with intravenous cannulation (the drip), blood tests (which will involve only one extra blood test) and intravenous fluid therapy. If for any reason the doctor thinks that it is not in a child's best interest to be in the study then they will not be enrolled in the study but will be given their usual treatment.

Where is the study run from?
Kilifi County Hospital (Kenya)

When is the study starting and how long is it expected to run for?
June 2016 to January 2018

Who is funding the study?
Institutional Strategic Support Fund, Imperial College London (UK)

Who is the main contact?
1. Dr Kirsty Houston (public)
2. Professor Kathryn Maitland (scientific)

Contact information

Type(s)
Public

Contact name
Dr Kirsty Houston

Contact details
PO Box 230
Clinical Trials Facility
Kilifi
Kenya
80108

Type(s)
Scientific

Contact name
Prof Kathryn Maitland

ORCID ID
https://orcid.org/0000-0002-0007-0645

Contact details
PO Box 230
Clinical Trials Facility
Kilifi
Kenya
80108

Additional identifiers

Protocol serial number
16IC3388 and KEMRI/SERU/CGMR-C.053/3299

Study information

Scientific Title
Gastroenteritis Aggressive versus Slow Treatment for RehydratiOn (GASTRO): a pilot rehydration study for severe dehydration: WHO plan C versus slower rehydration

Acronym
GASTRO

Study objectives
Slower intravenous rehydration is equally effective in rehydration but associated with fewer fluid related adverse effects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Imperial College (ICREC) - Original approval 18/08/2016, Ref 16IC3388, Amendment approved 16/09/2016
2. KEMRI SERU - Original approval 16/08/2016, Ref 053/3299, Amendment approved 20/10/2016
3. Poisons and Pharmaceuticals Board - Original approval 20/09/2016 (application made with amended protocol)
4. MRHREC - Original approval 28/11/2016
5. UNCST - awaited

Study design
A pilot phase II trial comparing slow versus standard (fast) intravenous rehydration of children admitted to hospital with gastroenteritis and severe dehydration

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Severe dehydration secondary to acute gastroenteritis

Interventions
Eligible children, whose parents have given consent (or verbal assent with deferred consent), will be randomized in a 1:1 ratio to one of two treatment arms. One arm will receive treatment as per the WHO recommendations, and the other arm will receive a slower rehydration regimen. All children will receive Ringers Lactate (as per WHO recommendations).

WHO Plan ‘C’ arm:
Children in the WHO Plan ‘C’ arm will be assessed for shock. Those who meet WHO criteria for shock will receive up to two 20ml/Kg boluses before starting treatment on Plan C. All children in the WHO Plan ‘C’ arm will receive 30ml/Kg (over 30mins if ≥1yr, and 1hour if <1yr) and then 70ml /Kg (over 2.5hrs if ≥1yr, and 5hours if <1yr)

GASTRO Slow Arm
There will be no fluid boluses given to children randomised to the GASTRO Slow Arm (regardless of features of shock). ALL children will receive 100mls/Kg over 8hours, regardless of age.

If the patient has ongoing GI losses then there will be a clinical review and the child may receive one further course of IV fluids as per the arm to which they have been randomized. If losses persist after this, fluids will be titrated as per the individual child’s fluid balance.

Patients will be offered oral fluids throughout the trial but, for the purposes of this trial, all will complete their prescribed intravenous fluid therapy.

Patients will have regular observations and clinical reviews. All patients will be followed up on Day 7 following admission.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Intravenous fluids (Ringers Lactate)

Primary outcome(s)
Frequency of fluid related significant adverse events including mortality, development of hypotensive shock, pulmonary oedema and neurological compromise measured using serial clinical and observational assessments at 1, 4, 8, 24 and 48 hours after admission.

Key secondary outcome(s))
1. Time to correction of dehydration as measured by the ability to take and retain oral fluids /feeds and who are in neutral or marginally positive fluid balance (both input and output will be measured). This will be deduced from hourly fluid balance charts, nursing records and clinical assessments
2. Time to pass urine and urine output measured by hourly urinary catheter bag volumes
3. Dysnatraemia at 8 hours measured by serum electrolyte sampling at admission, 8 and 24hours
4. Time to tolerate oral feeds as documented on hourly nursing observations
5. Time to discharge
6. Bioelectrical impedence analysis will be performed at 1, 24, 48hours and on day 7 review and will assess hydration status
7. Echocardiography will be performed at 1, 4, 8 and 24hours after admission and will assess cardiovascular responses to intravenous rehydration

Completion date
31/01/2018

Eligibility

Key inclusion criteria
Children, aged 60 days to 12 years, with acute gastroenteritis (> 3 loose stools/day over a period of <14days) and signs of severe dehydration (as per WHO definition – unable to drink or AVPU <A, with sunken eyes and reduced skin pinch (<2seconds) and an inability to take or retain oral fluids), with or without shock. Shock will be defined by the recent 2016 WHO ETAT criteria; a patient with two of all of the following: cold peripheries with a weak and fast pulse (rate not specified) and a capillary refill time >3 seconds.

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
122

Key exclusion criteria
1. Severe malnutrition (kwashiorkor or MUAC <11.5cm)
2. Diarrhoea lasting more than 14-days
3. Children with known congenital heart disease (or diagnosed on initial ECHO assessment)
4. Refusal of consent

Date of first enrolment
01/09/2016

Date of final enrolment
31/01/2018

Locations

Countries of recruitment
Kenya

Uganda

Study participating centre
Kilifi County Hospital
Kilifi County Hospital, KEMRI-Wellcome Trust Research Programme, CGMRC
Plot No. LR No. 5054/190
Hospital Road
Kilifi
Kenya
80108

Study participating centre
Mbale Regional Referral Hospital
Palisa Road
Mbale
Uganda
-

Study participating centre
Soroti Regional Referral Hospital
Soroti
Uganda
-

Sponsor information

Organisation
Imperial College London

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
University/education

Funder Name
Imperial College London

Alternative Name(s)

Imperial College of Science, Technology and Medicine, Imperial College London, UK, Imperial College London, London, England, Imperial College London in United Kingdom, imperialcollege, ICL

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2019	02/07/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes