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A randomised controlled trial of resistant starch as adjuvant to reduced osmolarity oral rehydration solution in the treatment of children with diarrhoea

Submission date
22/08/2007

Recruitment status
No longer recruiting

Registration date
23/08/2007

Overall study status
Completed

Last Edited
05/02/2015

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

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
036150

Study information

Scientific Title
A randomised controlled trial of resistant starch as adjuvant to reduced osmolarity oral rehydration solution in the treatment of children with diarrhoea

Study objectives
The hypothesis is that addition of amylase resistant starch as an adjunct to reduced osmolarity Oral Rehydration Solution (ORS) will significantly decrease stool fluid losses and shorten duration of diarrhoeal illness in children with non-cholera diarrhoea.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Single-centre randomised controlled single-blinded clinical trial with two arms

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Acute infective diarrhoea in children

Interventions
After informed consent from parents, eligible children will be randomised to receive standard treatment for diarrhoea including reduced osmolarity World Health Organisation (WHO) oral rehydration solution or reduced osmolarity WHO ORS solution containing High Amylose Maize Starch (HAMS) 50 grams per litre. Randomisation will be done in blocks of 40 and achieved by packing the appropriate ORS packets (suitable for reconstitution in 200 ml water) in sealed opaque covers bearing the study number. The randomisation and packaging will be done in Vellore and the study will be done in Kolkata.

Children will be rehydrated within the first 4 to 6 hours following standard guidelines, and administered their normal food including breast milk where applicable, after rehydration is completed. Supplements of zinc sulphate 20 mg per day will be given for 14 days. Clinical parameters of hydration will be monitored, urine output will be measured, and stool collected in diapers and weighed. Intravenous fluids can be administered during the trial at the discretion of the supervising paediatrician depending on clinical the indication and will be recorded as unscheduled IV fluid administration. Stool consistency will be graded and the study stopped when the stool is 'pasty' or 'formed'.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Osmolarity Oral Rehydration Solution (ORS)

Primary outcome measure
1. Stool output in first 48 hours
2. Duration of diarrhoea - time from onset of ORS administration to first formed stool

Secondary outcome measures
Need for unscheduled administration of IV fluids

Overall study start date
01/03/2007

Completion date
31/01/2008

Eligibility

Key inclusion criteria
1. Male children aged 6 months to 3 years
2. Diarrhoea (defined as greater than three watery stools/24 hours, with "some" dehydration) for three days or less
3. Children with severe dehydration may be included if stable after Intravenous (IV) rehydration

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Months

Upper age limit
3 Years

Sex
Male

Target number of participants
210

Key exclusion criteria
1. Bloody diarrhoea
2. Concurrent severe illness - pneumonia, meningitis or other severe infections
3. Grade II and IV malnutrition

Date of first enrolment
01/03/2007

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
India

Study participating centre
National Institute of Cholera and Enteric Diseases
Kolkata
India
700010

Sponsor information

Organisation
Christian Medical College (India)

Sponsor details
Department of Gastrointestinal Sciences
Williams Research Building
Ida Scudder Road
Vellore
India
632004
+91 (0)416 228 2052
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Sponsor type
Hospital/treatment centre

Website
http://www.cmch-vellore.edu

ROR
https://ror.org/00c7kvd80

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

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