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Additive effect of resistant starch on oral rehydration therapy and zinc supplementation for children with acute diarrhoea

Submission date	Recruitment status	[_] Prospectively registered
14/03/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/03/2007	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
05/02/2015	Infections and Infestations	[_] 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
063150

Study information

Scientific Title
Additive effect of resistant starch on oral rehydration therapy and zinc supplementation for children with acute diarrhoea

Study objectives
To determine if amylase resistant starch, specifically High-Amylose Maize Starch (HAMS), when added to standard World Health Organisation (WHO) Oral Rehydration Solution (ORS) and zinc supplementation, will be superior to standard ORS and zinc supplementation in reducing diarrhoeal duration or stool output in children with acute diarrhoea.

This trial will be conducted at two hospitals in Vellore, India. The hospitals, Christian Medical College Hospital, and Community Health And Development (CHAD) Hospital are both affiliated with Christian Medical College.

Patient Gender: Male and Female
Trial type: Treatment
Trial method: Randomised controlled trial
Intervention type: High amylose maize starch added to oral rehydration solution
Setting: Tertiary care hospital (CMC Hospital) and community hospital (CHAD)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board of CMC, Vellore (India), 27/01/2007, ref: IRB(EC)6/1/2007

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
Acute infectious diarrhoea

Interventions
Consecutive children presenting to the paediatric emergency room or outpatient clinics at CMC Hospital and CHAD, and fulfilling inclusion criteria, will be offered entry into the study. The admitting paediatrician together with a study nurse or study doctor will obtain informed consent from a parent or legal guardian upon admission. Those children for whom informed consent is obtained will be randomised to one of two treatment arms:
1. Standard ORS and zinc supplementation (control group)
2. HAMS-ORS and Zinc supplementation (experimental group)

Children with severe dehydration will also be treated with three to six hours of intravenous fluids as per WHO treatment plan C. Those children with severe dehydration who are not adequately rehydrated after the initial three to six hours of intravenous fluids, and require further intravenous hydration at this time will be excluded from the study.

Study numbers for each arm will be generated using a table of random numbers in blocks of ten patients. For practical reasons, subjects at CMC Hospital and CHAD Hospital will have site-specific randomisation blocks and distinct study numbers. Packets containing one of the two different therapies will be sealed with opaque covers bearing serial study numbers; children will be designated to treatment arms by the packet that they receive.

Treatment will be prepared and administered by study nurses. Standard ORS will be formulated according to WHO recommendations (sodium 75 mEq/L, potassium 20 mEq/L, chloride 65 mEq/L, glucose 75 mmol/L, citrate 10 mmol/L, osmolarity 245 mOsm/L) by adding a pre-formulated packet to 200 ml water. HAMS-ORS will have 10 g HAMS added to each 200 ml of standard ORS, yielding 50 g/L of HAMS. 20 mg zinc sulfate syrup (20 mg in 5 ml) will be administered to each child daily until cessation of diarrhoea.

Children will be offered ORS (standard ORS or HAMS-ORS) according to the appropriate WHO treatment plan based on their level of dehydration. As is standard of care, oral intake of water will be encouraged, as well as re-feeding after an initial rehydration period.

Children will be followed until cessation of diarrhoea. While in the hospital, stool consistency will be monitored serially by the patients family member, almost invariably the childs mother, who will be trained how to fill out a stool recording chart that documents time of each bowel movement and stool consistency, according to a modified Bristol Stool Scale. Upon entry to the study, the child's mother will be asked to indicate on the modified Bristol Stool Scale the 'normal' consistency of their child's stool when the child is healthy. End of diarrhoea is defined as the last unformed stool preceding either a 'normal' consistency stool as just described, or a 12-hour period without any bowel movement.

If children are discharged prior to cessation of diarrhoea, family members will continue to administer standard ORS or HAMS-ORS and zinc at home, and they will continue to document the time and consistency of each stool until the end of diarrhoea. They will be given instructions to return the completed stool-recording chart to a study nurse. Those who do not return will be called or visited at home.

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Amylase resistant starch and zinc supplementation

Primary outcome measure
Diarrhoeal duration, defined as time from the start of ORS consumption to the last unformed stool, or the last stool prior to a 12 hour period without any bowel movement.

Secondary outcome measures
1. Stool frequency
2. Diarrhoeal stool output measured by weight. This will be measured only in male children; due to anatomical considerations only male children can have urine collected separately in a urine pouch so that accurate stool weights collected can be measured in pre-weighed diapers
3. Proportion of children who recover from diarrhoea by 24 hours and 48 hours
4. The need for unscheduled intravenous hydration for recurrent severe dehydration
5. Adverse events

Overall study start date
05/03/2007

Completion date
05/12/2007

Eligibility

Key inclusion criteria
1. Age six months to three years with acute diarrhoea, defined as more than three episodes of watery stools in the last 24 hours
2. Clinically detectable dehydration to warrant hospital treatment

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Months

Upper age limit
3 Years

Sex
Both

Target number of participants
116

Key exclusion criteria
1. Blood and mucus in stool
2. Severe coexisting disease, including pneumonia, meningitis, or severe (grades III and IV)

malnutrition
3. Vomiting that precludes administration of oral rehydration solution
4. Children with severe dehydration who are still severely dehydrated after three to six hours of intravenous fluids as per WHO treatment plan C

Date of first enrolment
05/03/2007

Date of final enrolment
01/12/2007

Locations

Countries of recruitment
India

Study participating centre
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Sponsor information

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Sponsor type
University/education

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ROR
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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