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Comprehensive studies of a new improved oral rehydration solution for diarrhoeal disease: physiological and molecular studies, clinical trials, and acceptability and efficacy studies in a rural south Indian community

Submission date 22/07/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 22/07/2005	**Overall study status** Completed	
Last Edited 06/02/2015	**Condition category** Signs and Symptoms	

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
Comprehensive studies of a new improved oral rehydration solution for diarrhoeal disease: physiological and molecular studies, clinical trials, and acceptability and efficacy studies in a rural south Indian community

Study objectives
The hypothesis is that addition of amylase resistant starch to a low osmolarity Oral Rehydration Solution (ORS) will reduce the duration and severity of diarrhoea in a variety of diarrhoeal diseases including cholera and non-cholera diarrhoea. The studies consist of two randomised trials in adults and children respectively comparing the newly recommended low osmolar ORS to low osmolar ORS with added amylase resistant starch. The objective is to determine whether subjects in the trial arm will have reduced stool output and duration of diarrhoea.

The overall trial end date was changed from 15/03/2006 to 31/01/2007.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised single-blinded controlled clinical trial

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
Diarrhoea

Interventions
Eligible subjects will be randomised to one of two treatment arms to receive either reduced osmolarity ORS or reduced osmolarity ORS along with amylase resistant starch. All other treatment measures will be identical in the two groups. ORS will be administered according to World Health Organisation (WHO) treatment guidelines for management of acute diarrhoea. Stool consistency and weight will be determined by personnel unaware of the treatment received by the patient.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Amylase resistant starch, low osmolarity Oral Rehydration Solution (ORS)

Primary outcome measure
1. Stool weight in successive 12 hour periods
2. Stool weight in the second 24 hours
3. Time to last unformed stool
4. Requirement for unscheduled intravenous fluids

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/01/2005

Completion date
31/01/2007

Eligibility

Key inclusion criteria
In the adult study, all adult male patients presenting to the Emergency Service with acute severe watery diarrhoea of less than three days' duration, with moderate to severe dehydration, will be enrolled after informed written consent.

In a separate trial, male children aged six months to five years with diarrhoea (defined as more than three watery stools/24 hours) of three days or less, with mild or moderate dehydration, or those with severe dehydration who have received intravenous rehydration, will be enrolled after informed written consent from the parent.

Participant type(s)
Patient

Age group
Mixed

Sex
Male

Target number of participants
To be added

Key exclusion criteria
In the adult trial, subjects without clinical dehydration, those with presence of blood in stool, and presence of significant systemic illness unrelated to the diarrhoea, will be excluded.

In the children's trial, bloody diarrhoea, concurrent severe illness (such as pneumonia, meningitis or infections requiring antibiotics), and severe malnutrition Grade III and IV will be treated as exclusion criteria.

Date of first enrolment
01/01/2005

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
India

Study participating centre
Christian Medical College
Vellore
India
632004

Sponsor information

Organisation
Christian Medical College (India)

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Sponsor type
Hospital/treatment centre

Website
http://cmcvellore.ac.in

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	13/02/2008		Yes	No