

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
Registration date 22/07/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 06/02/2015	Condition category Signs and Symptoms	☐ 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
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

Primary study design

Interventional

Study design

Randomised single-blinded controlled clinical trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Mixed

Sex

Male

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)

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

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