

An effectiveness trial examining the addition of zinc to the current case management package of diarrhoea in a primary health care setting (India)

Submission date 12/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 01/02/2006	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 28/01/2019	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

ClinicalTrials.gov (NCT)

NCT00278681

Protocol serial number

HNI 04008

Study information

Scientific Title

Effectiveness of zinc supplementation plus oral rehydration salts compared with oral rehydration salts alone as a treatment for acute diarrhea in a primary care setting: a cluster randomized trial

Study objectives

Zinc supplementation together with Oral Rehydration Therapy (ORT) will:

1. Increase Oral Rehydration Sachet (ORS) use rates
2. Reduce antimicrobial use rates
3. Increase care seeking use rates during diarrhoea

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the World Health Organization (WHO) on the 4th April 2005.

Primary study design

Interventional

Study design

Evaluation-based, randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Diarrhoea

Interventions

Implementation of the zinc intervention (zinc and ORT versus ORT alone) at community and primary health care level (phase III) - one year. Formative research (phase I) and pilot intervention (phase II) have already been completed - one year.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Zinc

Primary outcome(s)

1. Oral Rehydration Sachet (ORS) use rates per cluster
2. Antimicrobial use rates per cluster

Key secondary outcome(s)

1. Diarrhoea prevalence
2. Duration and severity of diarrhoeal episodes
3. Hospitalisation rates (overall, for diarrhoea, for Acute Respiratory Infections [ARI])

Completion date

31/12/2006

Eligibility

Key inclusion criteria

All children with diarrhoea living in the study area.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Sex

All

Key exclusion criteria

As this study is an effectiveness study, looking at the impact of the intervention implemented in normal conditions, there is no exclusion criteria.

Date of first enrolment

01/08/2005

Date of final enrolment

31/12/2006

Locations

Countries of recruitment

India

Switzerland

Study participating centre

World Health Organization

Geneva-27

Switzerland

CH-1211

Sponsor information

Organisation

The Department of Child and Adolescent Health and Development (CAH)/World Health Organization (WHO) (Switzerland)

ROR

<https://ror.org/01f80g185>

Funder(s)

Funder type

Research organisation

Funder Name

The Department of Child and Adolescent Health and Development (CAH)/World Health Organization (WHO) (Switzerland)

Funder Name

United Nations Children's Fund (UNICEF) - India

Funder Name

Department of Biotechnology - Ministry of Sciences and Biotechnology (India)

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	01/05/2008	28/01/2019	Yes	No