ISRCTN96456353 https://doi.org/10.1186/ISRCTN96456353

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

Registration date
01/02/2006

Overall study status
Completed

Last Edited
28/01/2019

Condition category
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Olivier Fontaine

Contact details
World Health Organization
20, Avenue Appia
Geneva-27
Switzerland
CH-1211
+41 (0)22 791 28 94
fontaineo@who.int

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00278681

Secondary identifying numbers
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)
Ethcis approval received from the World Health Organization (WHO) on the 4th April 2005.

Study design
Evaluation-based, 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
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 measure
1. Oral Rehydration Sachet (ORS) use rates per cluster
2. Antimicrobial use rates per cluster

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

Overall study start date
01/08/2005

Completion date
31/12/2006

Eligibility

Key inclusion criteria
All children with diarrhoea living in the study area.

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
6000

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)

Sponsor details
20, Avenue Appia
Geneva-27
Switzerland
CH-1211
+41 (0)22 791 28 94
fontaineo@who.int

Sponsor type
Research organisation

Website
http://www.who.int

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

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