

Zinc supplementation during acute childhood diarrhoea: a cluster randomised trial in rural Pakistan

Submission date
08/02/2005

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
10/02/2005

Overall study status
Completed

☐ Statistical analysis plan

☐ Results

Last Edited
17/10/2007

Condition category
Infections and Infestations

☐ Individual participant data

☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

WHO/HN104006

Study information

Scientific Title

Study objectives

The hypothesis being tested is that distribution of zinc through existing government and private health care system will reduce incidence of childhood diarrhoea, and antibiotic use by at least 30%.

The objectives of this trial are:

1. To evaluate if the administration of zinc supplement for 14 days to children with acute diarrhoea will lead to:
 - 1.1. Reduction in use of Oral Rehydration Sachets (ORS) in the community, and
 - 1.2. Reduction in use of antibiotics and anti-diarrhoeal medications at the community level
2. To document the acceptance of the treatment as well as the adherence to the treatment instructions
3. Reduction in the severity of diarrhoea and improved recovery rates
4. Reduction in rates of hospitalisation and need for intravenous rehydration
5. Reduced child mortality due to diarrhoea

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the World Health Organization (WHO) Ethical Review Committee on the 26th January 2006.

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

Childhood diarrhoea

Interventions

Administration of 10 to 20 mg elemental zinc daily through oral rehydration versus the existing program of oral rehydration alone in management of acute diarrhoea for 14 days. No placebo is being used in the control clusters.

Intervention Type

Supplement

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Zinc supplementation

Primary outcome measure

1. ORS use rate
2. Antibiotic use rate
3. Overall drug use rate for diarrhoea
4. Incidence/prevalence of diarrhoea
5. Duration of diarrhoea/episodes in days
6. Duration of use of ORS, antibiotics and zinc
7. Prevalence /incidence of vomiting
8. Hospitalisation rate for diarrhoea
9. Hospitalisation rate for all causes
10. Total expenditure per household and per episode of diarrhoea

Secondary outcome measures

No secondary outcome measures

Overall study start date

26/01/2005

Completion date

26/01/2007

Eligibility**Key inclusion criteria**

1. Children with diarrhoea from 6 to 59 months and 2 to 6 months presenting to any health care facility including both public and private
2. Informed consent

Participant type(s)

Patient

Age group

Child

Lower age limit

2 Months

Upper age limit

59 Months

Sex

Both

Target number of participants

5000 children (2500 per group)

Key exclusion criteria

1. Chronic and recurrent diarrhoea
2. Children less than 2 months or above 5 years

Date of first enrolment

26/01/2005

Date of final enrolment

26/01/2007

Locations**Countries of recruitment**

Pakistan

Switzerland

Study participating centre**World Health Organization**

Geneva-27

Switzerland

CH 1211

Sponsor information**Organisation**

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

Sponsor details

20, Avenue Appia

Geneva-27

Switzerland

CH 1211

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 (CAH)/World Health Organization (WHO) (Switzerland)

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