

# 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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### Contact details

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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