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

Submission date	Recruitment status	[_] Prospectively registered
08/02/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/02/2005	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
17/10/2007	Infections and Infestations	[_] Record updated in last year

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
WHO/HNI04006

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.

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(s)

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

Key secondary outcome(s)
No secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
2 Months

Upper age limit
59 Months

Sex
All

Key exclusion criteria
1. Chronic and recurrent diarrhoea
2. Children less then 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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration