Zinc introduction trial in Bougouni District, Mali

Submission date	Recruitment status	Prospectively registered
01/02/2006	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
01/02/2006	Completed	Results
Last Edited	Condition category	Individual participant data
14/07/2021	Signs and Symptoms	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

Protocol serial number

HNI 4001

Study information

Scientific Title

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Study objectives

Zinc supplementation of diarrhoeic children, together with Oral Rehydration Therapy (ORT), will:

- 1. Increase ORT/Oral Rehydration Sachet (ORS) use rates
- 2. Decrease antimicrobial use rates

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received on 15/04/2005.

Study design

Evaluation-based, randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Diarrhoea

Interventions

Health Facility and Community Zinc and ORT versus ORT alone intervention (phase III). A one year, formative research (phase I) and one year pilot intervention have already been completed.

Intervention Type

Other

Phase

Phase III

Primary outcome(s)

- 1. ORS use rates per cluster
- 2. Antimicrobial use rates per cluster
- 3. Prevalence/incidence of diarrhoea per cluster

Key secondary outcome(s))

- 1. Percentage of children with diarrhoea treated with zinc
- 2. Percentage of children with diarrhoea treated with ORS/ORT
- 3. Percentage of children with diarrhoea treated with inappropriate antibiotics

Completion date

31/07/2006

Eligibility

Key inclusion criteria

All under five children with diarrhoea living in the study area.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Upper age limit

5 years

Sex

All

Key exclusion criteria

This is an implementation study looking at the effectiveness of a new intervention conducted as naturally as possible through the normal public health system and through already in place community health workers. This is not an efficacy study, therefore, there is no exclusion criteria as all children presenting with diarrhoea should receive the new intervention.

Date of first enrolment

01/08/2005

Date of final enrolment

31/07/2006

Locations

Countries of recruitment

Mali

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 States Agency for International Development (USAID) (USA)

Alternative Name(s)

U.S. Agency for International Development, Agency for International Development, USAID

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration