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Zinc introduction trial in Bougouni District, Mali

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HNI 4001

Study information

Scientific Title

-

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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures

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

Overall study start date
01/08/2005

Completion date
31/07/2006

Eligibility

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

Participant type(s)
Patient

Age group
Child

Upper age limit
5 Years

Sex
Both

Target number of participants
6000

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)

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 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

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