ISRCTN34307051 https://doi.org/10.1186/ISRCTN34307051

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

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Additional identifiers

Protocol serial number
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.

Primary study design
Interventional

Study design
Evaluation-based, randomised controlled trial

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