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The impact of improved sanitation on the diarrhoeal reduction of under-five children in Ethiopia

Submission date
22/01/2015

Recruitment status
No longer recruiting

Registration date
13/03/2015

Overall study status
Completed

Last Edited
18/06/2025

Condition category
Infections and Infestations

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Diarrhoea is a major killer of children aged under five, accounting for 11% of child deaths in 2013. Sanitation coverage is still exceedingly below target and lack of sanitation causes a large disease burden in many developing countries. However, as few studies have investigated the effect of improved sanitation on reducing diarrhoea in children under five, we do not know how much benefit improved sanitation would bring, especially for reducing child deaths. More evidence is required for appropriate resource allocation and also for formulating evidence-based health policy. We aim to find evidence of the impact of improved sanitation on diarrhoea in children under five.

Who can participate?
Households with children aged under five in Gurage zone, SNNPR state of Ethiopia.

What does the study involve?
A survey will be conducted in 48 Gotts (groups of households), of which 24 Gotts will be randomly allocated to the intervention group and the other 24 to the control group. During the first phase of the study the intervention group will receive improved sanitation and hygiene, and the control group will receive the improvements after the first phase is completed. For the second phase of the study the intervention group will have access to an improved water supply, and the control group will have access to the improved water supply after the second phase is completed.

What are the possible benefits and risks of participating?
No financial subsidies will be provided but we expect the participants will less likely to contract diarrhoea and it will eventually also benefit their neighbours. After the study is over, the water supply will be connected to all the Gotts, both for the intervention group and the control group.

Where is the study run from?
Enemor Ena district and Cheha district, Gurage zone, Ethiopia

When is the study starting and how long is it expected to run for?
February 2015 to February 2016

Who is funding the study?
Korea International Cooperation Agency

Who is the main contact?
Dr Seungman Cha
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effect of improved sanitation on diarrhoea incidence of under-five children in Grage zone, SNNPR state, Ethiopia using cluster randomized controlled trial

Study objectives
Improved sanitation will reduce the diarrhoeal incidence of under-five children in Gurage zone, SNNPR satte of Ethiopia by 50%.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethiopian federal government and the ministry of health of SNNPR state – approval pending

Study design
Intervention study using phased-in and factorial design: cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Diarrhoea

Interventions
The cluster randomized trial takes Gott as the randomization unit since it is expected to be a cluster in which improved sanitation and hygiene will bring impact on diarrhoea transmission across households. All the interventions will be applied on Gott-wide basis. Since the purpose of the intervention is to reduce diarrhea, Gott would be an appropriate dimension of transmission zone, where humans, vectors, and intermediate hosts are interacting and sharing a common pool of parasites. Of the 240 Gotts, 99 Gotts will be selected for project implementation of clean water supply, and hygiene and sanitation improvement by the selection criteria on the basis of the degree of needs. The 99 Gotts will be stratified by altitude, water and sanitation coverage, accessibility to the main road, and socioeconomic status. 48 Gotts will be selected for trial arms by restricted stratified randomization process. A baseline survey will be conducted in these 48 Gotts, of which 24 Gotts will be randomly assigned to intervention and the other 24 to control in the cluster randomized control trial design. For increasing the comparability of the groups in each arms, we will stratify 48 Gotts into blocks having similar underlying, pre-intervention, risks of diarrhoea and then randomize within each block.

For improved sanitation and hygiene, the project is to roll out only in the intervention arm for the first phase and then the control arm will receive the intervention after the first phase trial is completed. In addition, improved water will be supplied to the intervention arm for the second phase and the control will have access to improved water supply after the second phase trial is completed.

Intervention Type
Behavioural

Primary outcome measure
Diarrhoeal incidence of under-five children (cases /child*weeks). We will conduct a household-based survey 9 times throughout the sanitation-project period, roughly 10 months, meaning that

the household survey will be conducted every month. With regards to measuring the outcmes, diarrhoea will not be diagnosed by a laboratory-based test, instead it will be identified by mothers' or caretakers' self report on the basis of a strict definition developed by the WHO expert group. We will help mothers or caretakers record the incidence of diarrhoea on the spot by using a specially-devised calendar, rather than depending on their recall.

Secondary outcome measures
1. Uptake of improved latrine (%)
2. Utilization of improved latrine (%)

Overall study start date
01/02/2015

Completion date
01/02/2016

Eligibility

Key inclusion criteria
Households with children aged under 5 years

Participant type(s)
Other

Age group
Child

Upper age limit
5 Years

Sex
Both

Target number of participants
1200 households; all the children in the 1200 households

Key exclusion criteria
1. Households without under-five children
2. Households rejecting registration
3. Households rejecting filling in informed consent form

Date of first enrolment
17/10/2015

Date of final enrolment
27/11/2015

Locations

Countries of recruitment

Ethiopia

Korea, South

Study participating centre
Enemor Ena district and Cheha district, Gurage zone, Ethiopia
Ethiopia
-

Study participating centre
KOICA
825 Daewangpangyo-ro
Sujeong-gu
Seongnam-si Gyoungi-do
Seoungnam si
Korea, South
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Sponsor information

Organisation
Korea International Cooperation Agency

Sponsor details
825 Daewangpangyo-ro
Sejeong-gu
Seongman-si
Gyeonggi-do
Korea, South
461-833

Sponsor type
Government

ROR
https://ror.org/0106d7657

Funder(s)

Funder type
Government

Funder Name
Korea International Cooperation Agency

Alternative Name(s)
KOICA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Korea, South

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	18/04/2016		Yes	No
Other publications	cost-effectiveness findings	14/07/2020	23/04/2021	Yes	No
Results article		24/06/2021	04/04/2023	Yes	No
Other publications	Secondary analysis	27/06/2024	18/06/2025	Yes	No