

The impact of improved sanitation on the diarrhoeal reduction of under-five children in Democratic Republic of Congo

Submission date 21/02/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 13/03/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 20/09/2017	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Diarrhoea is a major killer of children under five, accounting for 11% of child death in 2013. Human waste and poor sanitation is also associated with worm infections, trachoma (a bacterial eye infection), lymphatic filariasis (a parasitic infection that leads to elephantiasis) and schistosomiasis. However, without a significant acceleration in progress, the Millennium Development Goals (MDG) target on sanitation coverage is unlikely to be met. Current trends show that the total number of people without access to improved sanitation will still be around 2.4 billion. The aim of this study is to find evidence for the impact of improved sanitation on diarrhoea for children under the age of five. This study will play a central role in speeding up a reduction in diarrhoea-specific disease and death amongst children across the globe by demonstrating clear evidence of effectiveness of improved sanitation with rigorous methodology.

Who can participate?

Households with at least one child under five and living in a study area.

What does the study involve?

Villages recruited to this study are divided into a number of "quartiers", or divisions. Each quartier is randomly allocated into one of two groups, the intervention group or the control group. A sanitation campaign is delivered to the people living in one of the intervention groups. The aim of this campaign is to increase the availability of latrines (a deep hole that is used as a toilet) using community-led total sanitation (CLTS) principles, where communities are encouraged to take steps to stop open defecation. Boreholes are drilled in all communities in either group. During this study, people in the intervention group are actively encouraged to use the improved latrine facilities voluntarily. As the principle of CLTS are being applied to this project, details latrine design and materials are developed by the community people themselves. Assessments include the incidence of diarrhoea in the under fives, improvements in latrine facilities and improvements in the number of people using the latrines.

What are the possible benefits and risks of participating?

No financial subsidies will be provided since the principle of Community Led Total Sanitation should be strictly complied with. It is expected that the participants will be less likely to contract diarrhoea and it will eventually benefit their neighbours also. After the study is over, water facilities will be connected for all in the community both for the intervention group and the control group.

Where is the study run from?

Idiofa health office, Bandundu province (Democratic Republic of Congo)

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

December 2014 to December 2015

Who is funding the study?

Korea International Cooperation Agency

Who is the main contact?

Dr Seungman Cha

jesusdongja@hanmail.net

Contact information

Type(s)

Scientific

Contact name

Dr Seungman Cha

Contact details

Siheungsi Siheungdaero 73-gil 11

Seoul

Korea, South

153-762

82-10-3959-3286

jesusdongja@hanmail.net

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 Idiofa territory, Bandundu province, DR Congo using cluster randomized controlled trial

Study objectives

Improved sanitation will reduce the diarrhoeal incidence of under-five children in Idiofa territory, Bandundu province, DR Congo by 50%.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

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

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Community

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

The coverage of improved sanitation is exceedingly low in many rural area of DR Congo although diarrhoea is the main killer of children under five.

Interventions

For intervention arms, sanitation campaign will be conducted for increasing latrine coverage using CLTS principle and boreholes will be drilled in the communities of both arms. Drilling boreholes will be undertaken in the second phase of the project.

Intervention Type

Behavioural

Primary outcome measure

Diarrhoeal incidence of under-five children (cases /child*weeks)

Secondary outcome measures

1. Uptake of improved latrine (%)
2. Utilization of improved latrine (%)

Overall study start date

15/12/2014

Completion date

31/12/2015

Eligibility

Key inclusion criteria

Household with children under five years

Participant type(s)

All

Age group

Child

Upper age limit

5 Years

Sex

Both

Target number of participants

720 households; all the children in the 720 households

Key exclusion criteria

1. Households rejecting registration
2. Households rejecting filling in informed consent form

Date of first enrolment

15/12/2014

Date of final enrolment

15/12/2015

Locations

Countries of recruitment

Congo, Democratic Republic

Study participating centre

Idiofa health office

Bandundu province

Congo, Democratic Republic

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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

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	19/09/2017		Yes	No