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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	[_] Prospectively registered [X] Protocol
Registration date 13/03/2015	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 20/09/2017	**Condition category** Digestive System	[_] Individual participant data [_] 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 activity 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Prevention

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 compaign will be conducted for increasing latrine coverage using CLTS principle and boreholdes 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(s)
Diarrhoeal incidence of under-five children (cases /child*weeks)

Key secondary outcome(s))
1. Uptake of improved latrine (%)
2. Utilization of improved latrine (%)

Completion date
31/12/2015

Eligibility

Key inclusion criteria
Household with children under five years

Participant type(s)
All

Healthy volunteers allowed
No

Age group

Child

Upper age limit
5 years

Sex
All

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

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

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