



Clinical Trial Details (PDF Generation Date :- Thu, 27 Jun 2019 00:21:56 GMT)

CTRI Number	CTRI/2017/09/009640 [Registered on: 05/09/2017] - Trial Registered Retrospectively	
Last Modified On	04/09/2017	
Post Graduate Thesis	Yes	
Type of Trial	Interventional	
Type of Study	Preventive	
Study Design	Cluster Randomized Trial	
Public Title of Study	SODIS Water Treatment Intervention to reduce childhood diarrhea:A Clustered Randomized Controlled Trial in Northwest Ethiopia	
Scientific Title of Study	Household water treatment by solar disinfection as a method of diarrhoeal disease prevention among under five children in Dabat district, northwest Ethiopia	
Secondary IDs if Any	Secondary ID	Identifier
	N/A	NIL
Details of Principal Investigator or overall Trial Coordinator (multi-center study)	Details of Principal Investigator	
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Source of Monetary or Material Support

Source of Monetary or Material Support	
> University of Gondar, Vice president for Research and community service. Email:kasuumare@gmail.com Phone:581141236 P.O.Box:196 Gondar, Ethiopia	

Primary Sponsor

Primary Sponsor Details	
Name	University of Gondar
Address	Gondar, Ethiopia
Type of Sponsor	Other [Government University]

Details of Secondary Sponsor

Name	Address
NA	NA

Countries of Recruitment

List of Countries
Ethiopia

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Takele Tadesse Adafirie	Dabat DHSS site, in 28Villages, Dabat district, Northwest Ethiopia	Dabat research Center, Dabat District, North Gondar Administrative Zone, Amhara Administrative Regional Sate, Northwest Ethiopia P.O.Box. 196 Not Applicable N/A	920256715 takeletadesse1627@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional Ethical Review Board of University of Gondar	Approved	17/04/2015	Yes

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	at the base line they were healthy.

Intervention / Comparator Agent

Type	Name	Details
Intervention	SODIS water treatment intervention	Households with under five children in the 14 clusters(Villages) enrolled for household water treatment intervention group for consecutive 6months.
Comparator Agent	Control group: Non SODIS water treatment user	Households with under five children in the 14 clusters(Villages) enrolled for non SODIS user for drinking water treatment for consecutive 6months.

Inclusion Criteria

Inclusion Criteria	
Age From	6.00 Month(s)
Age To	59.00 Month(s)
Gender	Both



	Details	Inclusion criteria:(i) geographical accessibility of a cluster area throughout the year; (ii) the average size of cluster was 28-30 children under five years; (iii) reliance only on untreated drinking water sources and (iv) no other special water quality management intervention
Exclusion Criteria	Exclusion Criteria	
	Details	Exclusion criteria of Participants: Children less than 6 months of age, and children who were received special diarrhea prevention/control programs in the study area.
Method of Generating Random Sequence	Coin toss, Lottery, toss of dice, shuffling cards etc	
Method of Concealment	Centralized	
Blinding/Masking	Not Applicable	
Primary Outcome	Outcome	Timepoints
	Childhood diarrhoea incidence	Data assessed biweekly bases: week1:24/01/2016 week2:08/02/2016 week3:23/02/2016 week4:09/03/2016 week5:24/03/2016 week6:08/04/2016 week7:23/04/2016 week8:08/05/2016 Week9:23/05/2016 week10:07/06/2016 week11:22/06/2016 week12:07/07/2016
Secondary Outcome	Outcome	Timepoints
	Not applicable	Not applicable
Target Sample Size	Total Sample Size=797 Sample Size from India=0 Final Enrollment numbers achieved (Total)=766 Final Enrollment numbers achieved (India)=0	
Phase of Trial	N/A	
Date of First Enrollment (India)	No Date Specified	
Date of First Enrollment (Global)	10/01/2016	
Estimated Duration of Trial	Years=0 Months=6 Days=0	
Recruitment Status of Trial (Global)	Completed	
Recruitment Status of Trial (India)	Completed	
Publication Details	du Preez M, Conroy RM, Ligondo S, Hennessy J, Elmore-Meegan M, Soita A, McGuigan KG: Randomized intervention study of solar disinfection of drinking water in the prevention of dysentery in Kenyan children aged under 5 years. Environmental science & technology 2011, 45(21):9315-9323. McGuigan KG, Samaiyar P, du Preez M, Conroy RM: High compliance randomized controlled field trial of solar disinfection of drinking water and its impact on childhood diarrhea in rural Cambodia. Environmental science & technology 2011, 45(18):7862-7867. Mausezahl D, Christen A, Pacheco GD, Tellez FA, Iriarte M, Zapata ME, Cevallos M, Hattendorf J, Cattaneo MD, Arnold B: Solar drinking water disinfection (SODIS) to reduce childhood diarrhoea in	



Brief Summary

rural Bolivia: a cluster-randomized, controlled trial. PLoS medicine 2009, 6(8):882.

The magnitude of diarrhoeal disease is high in developing countries where an estimated 801,000 children under five die due to diarrhea each year. Consumption of water from unimproved sources is a potential contributor of diarrhoeal diseases and their transmission. In sub-Saharan Africa, safe water coverage is less than 50% where about 319 million people lack access to improved water sources and an estimated 1.9 billion people rely on faecally contaminated drinking-water.

In Ethiopia, nearly 40 million people, most of them in rural areas, don't have access to safe drinking water. Even water safe at the source can be easily contaminated during collection, transport, and storage. However, more than 90% of households do not treat their drinking water at home. Such a situation would pose high public health risks of diarrhea to unble water users unless prompt intervention is implemented. Evidence revealed in different parts of Ethiopia indicated that the two-week period prevalence of diarrhea among under-five children ranged from 22.5 to 36.0%.

Installation of large scale water treatment plants in rural Ethiopia is difficult due to the scarcity of resources including poor infrastructure. Therefore, the situation demands implementation of alternative strategies such as easily applicable low-cost and environmental friendly household water treatment such as solar water disinfection (SODIS). Solar water disinfection (SODIS) where raw water is filled in polyethylene terephthalate (PET) bottles is one of the potential alternative household water treatment technologies that rely on the germicidal effects of sunlight and heat. However, SODIS is still largely unknown as a method of household water treatment technology in rural Ethiopia. So, evidence based health effect of SODIS intervention at household level is limited. The main purpose of this study is to examine the effect of SODIS intervention in reducing the burden of diarrhoeal disease among under-five children in rural community of northwest Ethiopia.

A community based clustered randomized controlled trial was conducted among children under five years of age in each community from January 10 to July 7, 2016. The SODIS intervention was designed according to the Swiss Federal Institute for Environmental Science and Technology (EWAG) published guideline. Initially, the study area was divided into two blocks ("block A" and "block B") with an adequate buffering zone between them. Potential clusters in the study area were exhaustively listed and sorted out the eligible clusters based on the preset selection criteria within the two blocks. Intervention and control blocks/arms were



randomly assigned through lottery systems. Clusters were also selected in each block based on lottery methods. In the eligible 28 clusters (villages), households with under-five children were randomly allocated to the intervention and control groups and then assigned within each of the 14 pairs of communities randomly to one of them. In each cluster, 28-30 children (778 in total) were enrolled within 568 households and followed up for 6 consecutive months. Nineteen data collectors with 6 supervisors approached the mother-child pairs in the selected households and completed the baseline survey with regard to socio-demographic, environmental, and behavioral characteristics of each household in the community and follow up study.

The primary outcome of the study is childhood diarrhea which is defined by WHO as “three or more loose or watery stools over the past 24 hours (or more frequently than it is normal for the individual). It was computed as the number of under five children (U5C) who are new cases of a diarrhoeal disease over a six months of follow up period divided into person-weeks observation at risk during the similar period of time. Data were collected biweekly bases.

This research is operated under the aegis of Institute of Public Health, College of Medicine and Health Sciences, University of Gondar, Ethiopia.

Clinical trial protocol registry system is not available in Ethiopia.