# Clinical Trial Details

**PDF Generation Date:** Sat, 11 Aug 2018 02:17:55 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
<table>
<thead>
<tr>
<th>Secondary ID</th>
<th>Identifier</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
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</table>

## Details of Principal Investigator or overall Trial Coordinator (multi-center study)

<table>
<thead>
<tr>
<th>Details of Principal Investigator</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>Bikes Destaw Bitew</td>
</tr>
<tr>
<td>Designation</td>
<td>Assistant professor</td>
</tr>
<tr>
<td>Affiliation</td>
<td>University of Gondar</td>
</tr>
<tr>
<td>Address</td>
<td>University of Gondar, College of Medicine and Health Sciences, Institute of Public Health, Ethiopia Azezo</td>
</tr>
<tr>
<td></td>
<td>196</td>
</tr>
<tr>
<td></td>
<td>Other</td>
</tr>
<tr>
<td>Phone</td>
<td>918785876</td>
</tr>
<tr>
<td>Fax</td>
<td></td>
</tr>
<tr>
<td>Email</td>
<td><a href="mailto:bikesdestaw2004@gmail.com">bikesdestaw2004@gmail.com</a></td>
</tr>
</tbody>
</table>

## Details Contact Person (Scientific Query)

<table>
<thead>
<tr>
<th>Details Contact Person (Scientific Query)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>Gashaw Andargie Biks</td>
</tr>
<tr>
<td>Designation</td>
<td>Associate Professor</td>
</tr>
<tr>
<td>Affiliation</td>
<td>University of Gondar</td>
</tr>
<tr>
<td>Address</td>
<td>Institute of Public Health, College of Medicine and Health Sciences, University of Gondar, Ethiopia Gondar</td>
</tr>
<tr>
<td></td>
<td>196</td>
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<tr>
<td></td>
<td>Other</td>
</tr>
<tr>
<td>Phone</td>
<td>913385423</td>
</tr>
<tr>
<td>Fax</td>
<td>581116221</td>
</tr>
<tr>
<td>Email</td>
<td><a href="mailto:gashawab@gmail.com">gashawab@gmail.com</a></td>
</tr>
</tbody>
</table>

## Details Contact Person (Public Query)

<table>
<thead>
<tr>
<th>Details Contact Person (Public Query)</th>
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<tbody>
<tr>
<td>Name</td>
<td>Yigzaw Kebede Gete</td>
</tr>
<tr>
<td>Designation</td>
<td>Professor</td>
</tr>
<tr>
<td>Affiliation</td>
<td>University of Gondar</td>
</tr>
<tr>
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<td></td>
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<tr>
<td></td>
<td>Other</td>
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</table>
Source of Monetary or Material Support
University of Gondar, Vice president for Research and community service.
Email: kasuamare@gmail.com Phone: 581141236 P.O.Box:196 Gondar, Ethiopia

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

Details of Secondary Sponsor
Name: NA
Address: NA

Countries of Recruitment
List of Countries
Ethiopia

Sites of Study
<table>
<thead>
<tr>
<th>Name of Principal Investigator</th>
<th>Name of Site</th>
<th>Site Address</th>
<th>Phone/Fax/Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>Takele Tadesse Adafirie</td>
<td>Dabat DHSS site, in 28 Villages, Dabat district, Northwest Ethiopia</td>
<td>Dabat research Center, Dabat District, North Gondar Administrative Zone, Amhara Administrative Regional State, Northwest Ethiopia P.O.Box: 196</td>
<td>920256715 <a href="mailto:takeletadesse1627@gmail.com">takeletadesse1627@gmail.com</a></td>
</tr>
</tbody>
</table>

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

Regulatory Clearance Status from DCGI
Status: Not Applicable
Date: No Date Specified

Health Condition / Problems Studied
Health Type: Healthy Human Volunteers
Condition: at the base line they were healthy.

Intervention / Comparator Agent
<table>
<thead>
<tr>
<th>Type</th>
<th>Name</th>
<th>Details</th>
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<tbody>
<tr>
<td>Intervention</td>
<td>SODIS water treatment intervention</td>
<td>Households with under five children in the 14 clusters (Villages) enrolled for household water treatment intervention group for consecutive 6 months.</td>
</tr>
<tr>
<td>Comparator Agent</td>
<td>Control group: Non SODIS water treatment user</td>
<td>Households with under five children in the 14 clusters (Villages) enrolled for non SODIS user for drinking water treatment for consecutive 6 months.</td>
</tr>
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Inclusion Criteria
<table>
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<tr>
<th>Age From</th>
<th>Age To</th>
<th>Gender</th>
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</thead>
<tbody>
<tr>
<td>6.00 Month(s)</td>
<td>59.00 Month(s)</td>
<td>Both</td>
</tr>
</tbody>
</table>
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
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
Childhood diarrhoea incidence

Timepoints
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
Not applicable

Timepoints
Not applicable

Target Sample Size
Total Sample Size=797
Sample Size from 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

Brief Summary
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.

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.