

A randomised controlled trial to assess the LifeStraw® Family household gravity filter

Submission date 20/05/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/06/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 23/02/2011	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Study objectives

The objectives of the study are:

1. To assess the effectiveness of the LifeStraw® Family household filter in preventing diarrhoeal diseases
2. To determine the effectiveness of the LifeStraw® household filter in reducing the bacterial load of drinking water
3. To evaluate the extent to which it is used correctly and consistently by, and is acceptable to, the target population
4. We will also measure longevity of the filter as it is used in a field setting

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from:

1. The London School of Hygiene and Tropical Medicine (LSHTM) Ethics Board on the 15th November 2007 (ref: 5206)
2. Ecole de sante publique, Democratic Republic of Congo on the 22nd January 2008 (ref: ESP/CE /004/2008)

Study design

Two-armed randomised placebo-controlled trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Diarrhoea

Interventions

A two-arm randomised placebo-controlled trial will be conducted over a 12-month period. The trial will include two groups of households: half of the participating households will receive the LifeStraw® filter and the other half will receive a filter which looks like the LifeStraw® filter but which does not remove pathogens from the water.

The placebo has the same outside components as the real filter but the filtering membranes inside the cartridge have been replaced by some extra piping to imitate the weight of the real cartridge and the flow coming out of it.

Within one month of distributing the filters, field investigators will visit each household once a month (i.e. 12 visits per household during the overall follow-up period) to conduct a health survey. They will record for each household member, whether she/he had experienced any illness in the past 7 days, prompting a list of symptoms - in which diarrhoea is included - if no answer was spontaneously given.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Diarrhoea longitudinal prevalence, measured as weekly period prevalence.

Key secondary outcome(s)

1. Use of device, measured every month
2. Bacterial load reduction in drinking water, measured every month
3. Acceptability, measured once at the end of the study

Completion date

30/06/2009

Eligibility**Key inclusion criteria**

Households including members of all ages living in the study communities.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Other

Sex

All

Key exclusion criteria

Households and individuals who treat their water in a way that is deemed effective to prevent diarrhoea (e.g. boiling, filtration with a state of the art filter, regular use of bleach).

Date of first enrolment

01/06/2008

Date of final enrolment

30/06/2009

Locations**Countries of recruitment**

United Kingdom

England

Congo, Democratic Republic

Study participating centre
DCVBU
London
United Kingdom
WC1E 7HT

Sponsor information

Organisation
Vestergaard Frandsen (Switzerland)

ROR
<https://ror.org/02fj56008>

Funder(s)

Funder type
Industry

Funder Name
Vestergaard Frandsen (Switzerland)

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?
Results article	results	10/09/2010		Yes	No