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

Submission date	<b>Recruitment status</b> No longer recruiting	Prospectively registered		
20/05/2008		☐ Protocol		
Registration date 12/06/2008	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	Individual participant data		
23/02/2011	Infections and Infestations			

# Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

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#### Contact details

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# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

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

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Other

## Study type(s)

Prevention

#### Participant information sheet

Not available in web format, please use the contact details below to request a patient information

#### 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 measure

Diarrhoea longitudinal prevalence, measured as weekly period prevalence.

#### Secondary outcome measures

- 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

# Overall study start date

01/06/2008

# Completion date

30/06/2009

# Eligibility

#### Key inclusion criteria

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

#### Participant type(s)

Patient

#### Age group

Other

#### Sex

Both

#### Target number of participants

240 households with around 1200 participants

#### 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

Congo, Democratic Republic

England

**United Kingdom** 

# Study participating centre

**DCVBU** 

London United Kingdom WC1E 7HT

# Sponsor information

## Organisation

Vestergaard Frandsen (Switzerland)

# Sponsor details

Head Office - Switzerland Chemin de Messidor 5 - 7 Lausanne Switzerland CH-1006 +41 (0)21 310 7333 info@vestergaard-frandsen.com

#### Sponsor type

Industry

#### Website

http://www.vestergaard-frandsen.com/

#### **ROR**

https://ror.org/02fj56008

# Funder(s)

## Funder type

Industry

#### Funder Name

Vestergaard Frandsen (Switzerland)

# **Results and Publications**

# Publication and dissemination plan

Not provided at time of registration

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?
Results article	results	10/09/2010		Yes	No