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

Submission date	Recruitment status	[_] Prospectively registered
20/05/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/06/2008	Completed	[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

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The placebo has the same outside components as the real filter but the filtering membranes inside the cartridge have been replaced by some extra piping to imitate the weight of the real cartridge and the flow coming out of it.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