

# Effect of a novel plant extract on the severity and duration of infectious diarrhoea in children and adults

<b>Submission date</b> 09/01/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 21/01/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 05/03/2019	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Infectious diarrhoea is a major threat to human health and treatment with antibiotics has led to resistant bacteria. Prevention and management of dehydration is standard care but does not reduce the duration of diarrhoea. The aim in this study is to assess the usefulness of a plant extract (LiveXtract) in reducing the duration of diarrhoea in children and adults.

### Who can participate?

Male patients, age 6 months old to 60 years old, presenting with acute diarrhoea

### What does the study involve?

Patients will be randomly allocated to one of two groups: LiveXtract mixed with ORS or water mixed with ORS. They will be monitored for up to 4 days.

### What are the possible benefits and risks of participating?

A benefit is the reduction in the duration of diarrhoea. A risk might be a reaction to the LiveXtract solution.

### Where is the study run from?

Dhaka Hospital (Bangladesh)

### When is the study starting and how long is it expected to run for?

From July 2011 to October 2017

### Who is funding the study?

LiveLeaf Inc (USA)

### Who is the main contact?

Dr Thomas Lawson  
tlawson@liveleaf.com

# Contact information

## Type(s)

Scientific

## Contact name

Dr Thomas Lawson

## ORCID ID

<http://orcid.org/0000-0001-5182-4681>

## Contact details

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# Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

PR-11036

# Study information

## Scientific Title

Assessment of the therapeutic effect of LiveXtract, a novel plant extract, on the severity and duration of infectious diarrhoea in children and adults: a randomised double-blind placebo-controlled study

## Study objectives

Use of the LiveXtract mixed with oral rehydration solution (ORS) will reduce the duration of diarrhoea compared with ORS alone.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

ICDDR,B Ethical Review Committee, 29/12/2011, PR-11036

## Study design

Interventional randomised double-blind placebo-controlled study

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

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

**Health condition(s) or problem(s) studied**

Diarrhoea

**Interventions**

1. LiveXtract solution mixed with ORS
2. Water mixed with ORS

**Intervention Type**

Supplement

**Primary outcome measure**

Reduction in the severity and duration of diarrhoea, measured as the time the stool is ranked as a 4 or less on the Bristol Stool Scale

**Secondary outcome measures**

1. Volume of ORS consumed from the time of randomisation to resolution of diarrhoea
2. Number of events and duration of emesis

These outcomes will be monitored every 6 hours for 4 days and ranked with a Visual Analogue Scale of 0 to 10.

**Overall study start date**

04/07/2011

**Completion date**

01/10/2017

## **Eligibility**

**Key inclusion criteria**

1. Age 6 months old to 60 years old
2. Acute watery diarrhoea (for 48 hours or less)

**Participant type(s)**

Patient

**Age group**

Mixed

**Sex**

Male

**Target number of participants**

The target total recruitment of participants is 736 patients.

**Total final enrolment**

85

**Key exclusion criteria**

1. Fever
2. Bloody stool with or without abdominal pain
3. Clinical signs of coexisting severe acute systemic illness
4. Underlying severe chronic disease
5. Severe malnutrition
6. Signs of internal bleeding or black stools
7. Signs of drug abuse
8. Food allergy or other chronic gastrointestinal disease
9. Use of antibiotics or any anti-diarrhoeal medication during the previous 2 weeks
10. Any condition that the admitting physician believes will place the patient at risk if enrolled in the study
11. Participants whose stool cultures show *Shigella* spp
12. Unable or unwilling to provide informed consent

**Date of first enrolment**

10/05/2012

**Date of final enrolment**

01/10/2017

**Locations****Countries of recruitment**

Bangladesh

**Study participating centre****Dhaka Hospital**

68 Shaheed Tajuddin Ahmed Sarani

Dahaka

Bangladesh

1212

# Sponsor information

## Organisation

LiveLeaf Inc

## Sponsor details

1160 Industrial Road  
Suite 11  
San Carlos  
United States of America  
94070  
+16505177288  
tlawson@liveleaf.com

## Sponsor type

Industry

## Website

<http://liveleaf.com>

## ROR

<https://ror.org/00m48tn76>

# Funder(s)

## Funder type

Industry

## Funder Name

Liveleaf Inc

# Results and Publications

## Publication and dissemination plan

This study is running in two phases: a pilot study for safety data, with submission of the results before April 2015; the second phase will begin in the summer of 2015 and is likely to last 18 months and these data will be submitted to a peer-reviewed journal before the end of 2016.

## Intention to publish date

30/04/2015

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/01/2015	05/03/2019	Yes	No