

# Effect of a bioactive solution on the duration of diarrhoea in 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 type="checkbox"/> Results
<b>Last Edited</b> 21/01/2015	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Diarrhoea rarely results in death in adults, but can affect a family's resources through extra health care costs and loss of wages. The current treatment (oral rehydration solutions [ORS]) reduces dehydration in patients but does not reduce the time to resolution of the diarrhoea. The aim in this study is to find out whether a bioactive solution can reduce the time an individual has diarrhoea.

### Who can participate?

Adults with acute, non-infectious diarrhoea for up to 48 hours

### What does the study involve?

Participants will be randomly allocated to one of two groups: ORS and water (control group) or a bioactive solution added to the ORS (test group) on day 1. They will be monitored for 5 days to find out the time to resolution of the diarrhoea.

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

A possible benefit is a shorter time to resolution of the diarrhoea. A possible risk is a reaction to the bioactive solution.

### Where is the study run from?

Community health clinic of Universidad Centroamericana de Ciencias Empresariales (Nicaragua)

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

From August 2011 to May 2012

### 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

1160 Industrial Road  
Suite 11  
San Carlos  
United States of America  
94070  
+16505177288  
[tlawson@liveleaf.com](mailto:tlawson@liveleaf.com)

# Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

20110201

# Study information

## Scientific Title

Assessment of the capability of a novel bioactive polyphenol solution on the duration of diarrhoea in adults: a randomised placebo-controlled study

## Study objectives

Consumption of a bioactive polyphenol solution will reduce the time to resolution of diarrhoea by 20%

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Institutional review board of the Universidad Centroamericana de Ciencias Empresariales, Managua, Nicaragua, 15/10/2011, 201113

Study design

Interventional randomised placebo-controlled trial at a single community health clinic

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Community

**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 in adults

**Interventions**

Patients will be randomly allocated to oral rehydration solution (ORS) and bioactive polyphenol solution or ORS and water on day 1 and then monitored for 5 days to determine the time for resolution of diarrhoea and any changes to gastrointestinal symptoms.

**Intervention Type**

Supplement

**Primary outcome measure**

Resolution of diarrhoea, assessed as the time that stool had a Bristol Stool Scale ranking of 4 or less

**Secondary outcome measures**

Change in ranking of abdominal pain and bloating between day 1 and day 5 and any adverse events, measured with the Visual Analogue Scale of 0 to 10

**Overall study start date**

08/08/2011

**Completion date**

15/05/2012

**Eligibility****Key inclusion criteria**

1. Age 18–80 years
2. Provided informed consent
3. Acute diarrhoea (for 48 hours or less)

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

The target total recruitment of participants was 150 patients.

**Key exclusion criteria**

1. History of uncontrolled emesis
2. Signs of coexisting acute systemic illness (e.g., sepsis or pneumonia)
3. Underlying chronic disease (e.g., heart disease or diabetes)
4. Food allergies or other chronic gastrointestinal diseases
5. Use of probiotic agents in previous 3 weeks
6. Use of antibiotics or anti-diarrhoeal medication in previous 2 weeks
7. Severely malnourished
8. Showed signs of internal bleeding or drug abuse
9. Any condition the physician believed would put the patient at risk if given only standard treatment for diarrhoea
10. Unwilling or unable to provide informed consent

**Date of first enrolment**

15/01/2012

**Date of final enrolment**

10/05/2012

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

Nicaragua

**Study participating centre**

Community health clinic of Universidad Centroamericana de Ciencias Empresariales

Managua

Nicaragua

**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**

Plan is to publish in a peer-reviewed journal indexed by PubMed.

**Intention to publish date**

30/03/2015

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Available on request