ISRCTN57765025 https://doi.org/10.1186/ISRCTN57765025

# Effect of a bioactive solution on the duration of diarrhoea in adult and paediatric patients

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| **Submission date**<br>09/01/2015 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>21/01/2015 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[X] Results |
| **Last Edited**<br>09/02/2023 | **Condition category**<br>Digestive System | [X] Individual participant data |

## Plain English summary of protocol

Background and study aims
Diarrhoea is a leading cause of death in children, and results in health decline and time lost at work for adults. Oral rehydration solution (ORS) is the standard of care for individuals with non-infectious diarrhoea. It reduces the dehydration caused by diarrhoea, but does not reduce the time to resolution of diarrhoea. The aim of the study is to test whether adding a novel polyphenol solution to ORS might reduce the time to resolution of the diarrhoea compared with the resolution time with ORS alone.

Who can participate?
Adults and children with diarrhoea for less than 48 hours

What does the study involve?
Participants will receive ORS plus the polyphenol solution or ORS plus water once at the start of 2 days and the resolution of diarrhoea and other intestinal symptoms will be recorded.

What are the possible benefits and risks of participating?
The benefits are the reduction of the duration of diarrhoea with no side-effects. The risk is that a patient might have an adverse event to the polyphenol solution.

Where is the study run from?
Community clinic associated with the Universidad Centroamericana de Ciencias Empresariales (Nicaragua)

When is the study starting and how long is it expected to run for?
From February 2010 to December 2010.

Who is funding the study?
LiveLeaf Inc (USA).

Who is the main contact?
Dr Thomas Lawson
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# Contact information

### Type(s)
Scientific


### Contact name
Dr Thomas Lawson

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
20110101

# Study information

### Scientific Title
Assessment of a bioactive polyphenol solution on the duration of acute diarrhoea in adult and paediatric patients: a randomised double-blind placebo-controlled crossover study

### Study objectives
Consumption of a bioactive polyphenol solution will reduce the duration of acute 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), 10/05/2010, 201005

### Study design

Randomised double-blind placebo-controlled crossover study

### Primary study design
Interventional

### Secondary study design
Randomised cross over 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
Acute diarrhoea (for less than 48 hours)

### Interventions
1. Oral rehydration solution and bioactive solution on day 1 and then oral rehydration solution and water (placebo) on day 2
2. Oral rehydration solution and water (placebo) on day 1 and then oral rehydration solution and bioactive polyphenol solution on day 2

### Intervention Type
Supplement

### Primary outcome measure
Resolution to diarrhoea, assessed as the time from ingestion of the solution to when an individual produced a stool with a Bristol Stool Scale ranking of 4 or less.

### Secondary outcome measures
1. Defecation urgency, ranked from 0 (none) to 10 (extreme) at the various time intervals by patients (adults) and caregivers (for children)
2. Bloating or gas, ranked from 0 (none) to 10 (extreme) at the various time intervals by patients (adults) and caregivers (for children)
3. Abdominal pain at 30, 60, 90 and 120 minutes after consumption of the solutions on day 1 and day 2; pain was ranked from 0 to 10 on the Visual Analogue Scale

### Overall study start date
12/02/2010

### Completion date
07/12/2010

## Eligibility

### Key inclusion criteria
1. 5–80 years old
2. Diarrhoea for less than 48 hours

### Participant type(s)
Patient

### Age group
All

### Sex
Both

### Target number of participants
The target total recruitment of participants was 200 patients.

### Total final enrolment
61

### Key exclusion criteria
1. History of uncontrolled emesis
2. Grossly bloody stool
3. Fever
4. Clinical signs of a coexisting acute systemic illness (e.g., meningitis, sepsis or pneumonia)
5. Underlying chronic disease (e.g., heart disease, cystic fibrosis or diabetes)
6. Food allergies or other chronic gastrointestinal diseases
7. Use of probiotic agents in the previous 3 weeks or antibiotics or anti-diarrhoeal medications including over-the-counter and herbal substances in the previous 2 weeks
8. Generalised cachexia
9. Any signs of internal bleeding or drug abuse
10. Any condition, assessed with a standard of care, to cause unnecessary risk if participant given oral rehydration solution alone
11. Unable or unwilling to provide informed consent

### Date of first enrolment
14/09/2010

### Date of final enrolment
07/12/2010

## Locations

### Countries of recruitment
Nicaragua

### Study participating centre

**Community health clinic of Universidad Centroamericana de Ciencias Empresariales**
Managua
Nicaragua
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# Sponsor information

**Organisation**
LiveLeaf Inc

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**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**
Publish the results from the study in a peer-reviewed journal that is indexed in PubMed

**Intention to publish date**

30/03/2015

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request

## IPD sharing plan summary

Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 21/05/2015 | 05/03/2019 | Yes | No |
| Dataset | | | 09/02/2023 | No | No |