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

Submission date 09/01/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 21/01/2015	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 09/02/2023	**Condition category** 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

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)
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.

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
All

Sex
All

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

ROR
https://ror.org/00m48tn76

Funder(s)

Funder type

Industry

Funder Name
LiveLeaf Inc

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes