

Effect of a bioactive solution on the duration of diarrhoea in adults

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 ☐ Results
Last Edited 21/01/2015	Condition category Digestive System	☐ Individual participant data ☐ 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
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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

ROR

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

Funder(s)

Funder type

Industry

Funder Name

LiveLeaf Inc

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request