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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 [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 21/01/2015	**Overall study status** Completed	
Last Edited 21/01/2015	**Condition category** Digestive System	

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

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Dr Thomas Lawson

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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 sytemic 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

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Sponsor type
Industry

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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