ISRCTN11621877 https://doi.org/10.1186/ISRCTN11621877

Effect of a novel plant extract on the severity and duration of infectious diarrhoea in children and adults

Submission date
09/01/2015

Recruitment status
No longer recruiting

Registration date
21/01/2015

Overall study status
Completed

Last Edited
05/03/2019

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Infectious diarrhoea is a major threat to human health and treatment with antibiotics has led to resistant bacteria. Prevention and management of dehydration is standard care but does not reduce the duration of diarrhoea. The aim in this study is to assess the usefulness of a plant extract (LiveXtract) in reducing the duration of diarrhoea in children and adults.

Who can participate?
Male patients, age 6 months old to 60 years old, presenting with acute diarrhoea

What does the study involve?
Patients will be randomly allocated to one of two groups: LiveXtract mixed with ORS or water mixed with ORS. They will be monitored for up to 4 days.

What are the possible benefits and risks of participating?
A benefit is the reduction in the duration of diarrhoea. A risk might be a reaction to the LiveXtract solution.

Where is the study run from?
Dhaka Hospital (Bangladesh)

When is the study starting and how long is it expected to run for?
From July 2011 to October 2017

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

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PR-11036

Study information

Scientific Title
Assessment of the therapeutic effect of LiveXtract, a novel plant extract, on the severity and duration of infectious diarrhoea in children and adults: a randomised double-blind placebo-controlled study

Study objectives
Use of the LiveXtract mixed with oral rehydration solution (ORS) will reduce the duration of diarrhoea compared with ORS alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
ICDDR,B Ethical Review Committee, 29/12/2011, PR-11036

Study design

Interventional randomised double-blind placebo-controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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

Interventions
1. LiveXtract solution mixed with ORS
2. Water mixed with ORS

Intervention Type
Supplement

Primary outcome measure
Reduction in the severity and duration of diarrhoea, measured as the time the stool is ranked as a 4 or less on the Bristol Stool Scale

Secondary outcome measures
1. Volume of ORS consumed from the time of randomisation to resolution of diarrhoea
2. Number of events and duration of emesis
These outcomes will be monitored every 6 hours for 4 days and ranked with a Visual Analogue Scale of 0 to 10.

Overall study start date
04/07/2011

Completion date
01/10/2017

Eligibility

Key inclusion criteria
1. Age 6 months old to 60 years old
2. Acute watery diarrhoea (for 48 hours or less)

Participant type(s)
Patient

Age group
Mixed

Sex
Male

Target number of participants
The target total recruitment of participants is 736 patients.

Total final enrolment
85

Key exclusion criteria
1. Fever
2. Bloody stool with or without abdominal pain
3. Clinical signs of coexisting severe acute systemic illness
4. Underlying severe chronic disease
5. Severe malnutrition
6. Signs of internal bleeding or black stools
7. Signs of drug abuse
8. Food allergy or other chronic gastrointestinal disease
9. Use of antibiotics or any anti-diarrhoeal medication during the previous 2 weeks
10. Any condition that the admitting physician believes will place the patient at risk if enrolled in the study
11. Participants whose stool cultures show Shigella spp
12. Unable or unwilling to provide informed consent

Date of first enrolment
10/05/2012

Date of final enrolment
01/10/2017

Locations

Countries of recruitment
Bangladesh

Study participating centre
Dhaka Hospital
68 Shaheed Tajuddin Ahmed Sarani
Dahaka
Bangladesh
1212

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
This study is running in two phases: a pilot study for safety data, with submission of the results before April 2015; the second phase will begin in the summer of 2015 and is likely to last 18 months and these data will be submitted to a peer-reviewed journal before the end of 2016.

Intention to publish date
30/04/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2015	05/03/2019	Yes	No