

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	☐ Prospectively registered ☐ Protocol
Registration date 21/01/2015	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 05/03/2019	Condition category Digestive System	☐ 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
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Contact information

Type(s)

Scientific

Contact name

Dr Thomas Lawson

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Interventional randomised double-blind placebo-controlled study

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Mixed

Sex

Male

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

Dhaka

Bangladesh

1212

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

Study outputs

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