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Enterosgel® in treatment of acute diarrhoea in adults

Submission date	Recruitment status	[X] Prospectively registered
18/11/2016	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/11/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/08/2022	Infections and Infestations	

Plain English summary of protocol

Background and study aims
Every year several million people in the UK suffer from intestinal infections resulting in acute (severe) diarrhoea and other symptoms (i.e. vomiting, nausea). The symptoms usually stop after a few days, but can be unpleasant. Antidiarrheal medications can slow down the bowel movements, but there is a need for treatments which could reduce the duration of diarrhoea and other symptoms and be used in both children and adults. In some European countries, intestinal adsorbents are commonly used for treating diarrhoea. One of these products is Enterosgel®, which is available over-the-counter in the UK and has been reported to remove harmful substances like bacterial toxins and allergens from the gut. However, there is limited data on its effectiveness at reducing the duration of diarrhoea and other symptoms associated with intestinal infections. The aim of this study is to collect more data about the potential benefits of using Enterosgel® in the treatment of acute diarrhoea and associated symptoms.

Who can participate?
Patients aged 18 to 70 with acute diarrhoea

What does the study involve?
Participants are randomly allocated into two groups. One group receives Enterosgel® in addition to standard rehydration treatment and the other group receive only standard rehydration treatment. The duration of the study is 1 week and involves attending one study visit at the medical practice, followed by phone calls with the research nurse every morning for the next 7 days. Participants are asked to provide a stool sample and to keep a daily diary about their symptoms and use of treatments.

What are the possible benefits and risks of participating?
It is not known whether there will be any direct benefit to the participants. However, the findings from this study can benefit the participants and other patients in the future by providing information about the effectiveness of intestinal adsorbents in the treatment of diarrhoea and associated symptoms. The patients will receive enhanced care during the study as they will speak to a healthcare professional every day. No risks are foreseen and it does not

involve withholding any normal routine care procedures. The treatments used in this study are part of routine care (oral rehydration treatment) or products available over the counter and used in this study in their licensed purpose (Enterosgel).

Where is the study run from?
1. The Village Practice Thornton Medical Centre (UK)
2. West Walk Surgery (UK)
3. Pickering Medical Practice (UK)
4. Queen Square Medical Practice (UK)
5. Rowden Medical Partnership (UK)
6. Friarsgate Practice (UK)
7. Sherbourne Medical Centre (UK)
8. Cripps Health Centre (UK)
9. Chawton Park Surgery (UK)
10. Paxton Medical Group (UK)

When is the study starting and how long is it expected to run for?
September 2016 to July 2018

Who is funding the study?
Bioline Products s.r.o. (Czech Republic)

Who is the main contact?
Mrs Elena Markaryan

Contact information

Type(s)
Public

Contact name
Mrs Elena Markaryan

Contact details
85 Great Portland Street, First floor
London
United Kingdom
W1W 7LT

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ENT02UK

Study information

Scientific Title
Randomised, multi-centre study to assess efficacy, tolerability and safety of Enterosgel® in treatment of acute diarrhoea in adults

Study objectives
Over-the-counter intestinal adsorbent, Enterosgel®, used together with standard of care oral rehydration treatment is more effective in the treatment of acute diarrhoea than oral rehydration treatment alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West - Lancaster Research Ethics Committee, 01/12/2016, ref: 16/NW/0818

Study design
Randomised multi-centre post-marketing efficacy and safety study

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Acute diarrhoea

Interventions
This is a 1-week randomised, multi-centre, post-marketing efficacy and safety study of a medical device used within its intended purpose. As in many medical device studies, use of placebo in this trial would be difficult. The exploratory treatment is an orally consumed organosilicon gel-like product, and similar products without any potential impact on the study outcomes and with a demonstrated safety profile would be challenging to develop. As all efficacy and safety data will be recorded in patient diaries, the study outcomes will not be subject to assessor bias. The outcomes have been defined to be as standardised as possible in order to minimise any bias resulting from the participants being unblinded.

Patients will be randomised in 1:1 ratio to:
1. Control group: will receive a prescription for standard of care oral rehydration treatment (ORS)
2. Intervention group: will receive a prescription for standard of care ORS treatment together with an intestinal adsorbent, over-the-counter medical device, Enterosgel® (Bioline Products s.r. o, Czech Republic) to be taken according to study-specific dosage instructions for 5-7 days.

Enterosgel study-specific dosage instructions are as follows:
Day 0: First dose (as soon as possible): 2 tablespoons or 2 sachets of Enterosgel®. After the first dose: 1 tablespoon or 1 sachet of Enterosgel® after every bowel movement up to a total of 6 times and at least 3 times a day
Day 1: If loose stool more than once a day: 1 tablespoon or 1 sachet of Enterosgel® after every bowel movement up to a total of 6 times and at least 3 times a day; If no loose stool or just once a day: 1 tablespoon or 1 sachet of Enterosgel® 3 times a day
Days 2, 3, 4 and 5: If loose stool more than once a day: 1 tablespoon or 1 sachet of Enterosgel® 3 times a day; If no loose stool or just once a day: 1 tablespoon or 1 sachet of Enterosgel® 1-2 times a day
Days 6 and 7: If loose stool more than once a day: 1 tablespoon or 1 sachet of Enterosgel® 3 times a day; If no loose stool or just once a day: Stop taking Enterosgel®

Duration of the study is 1 week and will involve attending one study visit at the medical practice, followed by phone calls with the research nurse every morning for the next 7 days. The visit will involve confirmation of eligibility, informed consent and assessment of symptoms and relevant disease history. Patients will also be asked to provide a stool sample and to keep a daily diary about their symptoms and manifestations and use of treatments.

A patient diary is provided to collect the data for all efficacy outcomes and serves as the source data. The diary should be filled by the patients daily and returned to the practice at the end of the study. It contains fields to record the times of bowel movements and the consistency of stools, occurrence of nausea, vomiting, body temperature in the morning and evening, abdominal pain and any other symptoms. Treatment use will also be recorded in the patient diary.

Any AEs related to taking study treatment(s) should also be recorded in the patient diary. Any diarrhoea-related complications resulting in hospitalisation, Accident & Emergency department visit, nurse/GP home visit or unscheduled visit to the medical practice, should be reported by the patient during follow-up calls and recorded by the nurse in practice medical notes and the eCRF.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
Duration of acute diarrhoea, measured using daily patient diaries throughout the study

Secondary outcome measures
Current secondary outcome measures as of 11/06/2018:
1. Percentage of patients with diarrhoea resolved on Day 3 (i.e. first soft or firm stool recorded on Day 0-3)
2. Stool frequency, defined as the average number of stools/day from randomisation to first soft

or firm stool
3. Tolerance and safety of Enterosgel®, assessed via Adverse Event (AE) reporting from start of treatment until end of Day 7
4. Percentage of patients with diarrhoea-related complications resulting in hospitalisation, Accident & Emergency department visit, nurse/GP home visit or unscheduled visit to the medical practice from randomisation until end of Day 7
5. Duration (days) of the following from randomisation:
5.1. Nausea
5.2. Vomiting
5.3. High body temperature defined as ≥38°C
5.4. Abdominal pain
All outcomes measured using daily patient diaries throughout the study

Previous secondary outcome measures:
1. Percentage of patients with diarrhoea resolved on Day 3 (i.e. first soft or firm stool recorded on Day 0-3)
2. Stool frequency, defined as the average number of stools/day from first intake of treatment to first soft or firm stool
3. Tolerance and safety of Enterosgel®, assessed via Adverse Event (AE) reporting from start of treatment until end of Day 7
4. Percentage of patients with diarrhoea-related complications resulting in hospitalisation, Accident & Emergency department visit, nurse/GP home visit or unscheduled visit to the medical practice from start of treatment until end of Day 7
5. Duration (days) of the following from first intake of treatment:
5.1. Nausea
5.2. Vomiting
5.3. High body temperature defined as ≥38°C
5.4. Abdominal pain
All outcomes measured using daily patient diaries throughout the study

Overall study start date
01/09/2016

Completion date
18/07/2018

Eligibility

Key inclusion criteria
Current inclusion criteria as of 19/05/2017:
1. Informed consent
2. Patient-reported episode of acute diarrhoea defined as at least 3 watery stools within the last 48 hours
3. Aged 18 to 70
4. Willing and able to comply with the study protocol and evaluation(s) specified in the protocol
5. Considered suitable to take part in the study by the consenting GP/nurse (based on medical history and physical examination)

Previous inclusion criteria:
1. Informed consent
2. Patient-reported episode of acute diarrhoea defined as at least 3 watery stools within the last

48 hours
3. Aged 18 to 55
4. Willing and able to comply with the study protocol and evaluation(s) specified in the protocol
5. Considered suitable to take part in the study by the consenting GP (based on medical history and physical examination)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
104

Total final enrolment
105

Key exclusion criteria
1. History of intestinal atony (severe constipation due to bowel obstruction)
2. Blood in stools
3. Any underlying condition that could cause chronic diarrhoea (such as gastroduodenal ulcer, ulcerative colitis, or Crohn’s disease)
4. Patients with known cancer of any localisation
5. Use of any clinical trial investigational medication within the last 30 days before screening visit
6. Use of antibiotics since the onset of current diarrhoea episode
7. Pregnancy
8. A history of clinically significant allergic reactions
9. Any underlying condition that could affect the patient’s participation in this study or the results of this study in the investigator’s opinion

Date of first enrolment
01/12/2016

Date of final enrolment
15/12/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Village Practice Thornton Medical Centre
United Kingdom
FY5 2TZ

Study participating centre
West Walk Surgery
United Kingdom
BS37 4AX

Study participating centre
Pickering Medical Practice
United Kingdom
YO18 8BL

Study participating centre
Queen Square Medical Practice
United Kingdom
LA1 1RP

Study participating centre
Rowden Medical Partnership
Rowden Hill
Chippenham
United Kingdom
SN15 2SB

Study participating centre
Friarsgate Practice
Stockbridge Road
Weeke
Winchester
United Kingdom
SO22 6EL

Study participating centre
Sherbourne Medical Centre
40 Oxford St

Leamington Spa
United Kingdom
CV32 4RA

Study participating centre
Cripps Health Centre
University Park
Nottingham
United Kingdom
NG7 2QW

Study participating centre
Chawton Park Surgery
Chawton Park Rd
Alton
United Kingdom
GU34 1RJ

Study participating centre
Paxton Medical Group
Claughton Medical Centre
161 Park Road North
Birkenhead
United Kingdom
CH41 0DD

Sponsor information

Organisation
Enteromed Ltd

Sponsor details
85 Great Portland Street
First Floor
London
United Kingdom
W1W 7LT

Sponsor type
Industry

ROR
https://ror.org/013bz8f47

Funder(s)

Funder type
Industry

Funder Name
Bioline Products s.r.o.

Results and Publications

Publication and dissemination plan
Study results will be submitted for presentation(s) at gastroenterology conference(s) and for publication in international peer-reviewed scientific journal(s).

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study are available from Mrs Elena Markaryan on reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/04/2019	14/06/2019	Yes	No
Protocol file	version 1.4	11/06/2018	11/08/2022	No	Yes
HRA research summary			28/06/2023	No	No