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Enterosgel® in the treatment of functional abdominal pain in children and young people

Submission date
07/04/2025

Registration date
21/05/2025

Last Edited
12/11/2025

Recruitment status
Recruiting

Overall study status
Ongoing

Condition category
Digestive System

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Functional Abdominal Pain has become more common in children and young people. These are defined as “Functional Abdominal Pain Disorders” and include Functional Dyspepsia, Irritable Bowel Syndrome, Abdominal Migraine and Functional Abdominal Pain Not Otherwise Specified. There is no cure for these conditions and an important part of management aims to reduce symptoms and improve quality of life.
Enterosgel® is an intestinal adsorbent taken by mouth that binds bacterial toxins, and harmful substances in the gut. In the UK it is used for the treatment of acute diarrhoea and irritable bowel syndrome with diarrhoea, in people of all ages. It has been shown to reduce diarrhoea and improve abdominal pain and other gut symptoms. Enterosgel® is classified as a medical device class II (not as a medicine) because it is not adsorbed by the body and is excreted in the stools. Enterosgel® is available over the counter or on prescription as a gel in a tube or sachet and has no taste.
A recent study suggests that Enterosgel® can improve abdominal pain and diarrhoea in patients with irritable bowel syndrome. However, a study is needed to investigate the potential benefits of Enterosgel® in the treatment of Functional Abdominal Pain Disorders in children.

Who can participate?
This study aims to recruit 154 children and young people (age 3-18yrs) to see whether or not Enterosgel® may help with Functional Abdominal Pain.

What does the study involve?
The goal is to investigate whether children can take Enterosgel® and measure if they experience a reduction in their pain symptoms and improvement in their quality of life. The study lasts for 10 weeks and has a baseline phase to collect data on symptoms (2weeks), a double-blind phase where children will take placebo or Enterosgel® (4 weeks), followed by an open label phase where all children will take Enterosgel® for 4 weeks.

What are the possible benefits and risks of participating?
The study may benefit children and young people in helping to relieve their abdominal pain and improve their quality of life. The possible risks are very low, as Enterosgel® has clinical evidence of safety and efficacy of use in this age group and for a similar condition.

Where is the study run from?
Alder Hey Children's NHS Foundation Trust and Bristol Royal Hospital for Children (UK).

When is the study starting and how long is it expected to run for?
April 2025 to February 2027

Who is funding the study?
Bioline Products s.r.o.

Who is the main contact?
Dr Carol Howell, Trial manager, research@enteromed.co.uk

Contact information

Type(s)
Public, Scientific

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Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
356725

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
ENT08UK, CPMS 68074

Study information

Scientific Title
Randomised, placebo-controlled study to assess the safety and efficacy of ENterosgel® in the Treatment Of functional abdominal Pain In Children and young people

Acronym
ENTOPIC

Study objectives
Enterosgel reduces abdominal pain more than placebo in children and young people with Functional abdominal pain disorders.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 01/07/2025, Health and Social Care Research Ethics Committee A (HSC REC A) (Lissue Industrial Estate West, 5 Rathdown Walk, Lisburn, Co. Antrim, BT28 2RF, United Kingdom; +44 (028) 95 361400; reca@hscni.net), ref: 25/NI/0085

Study design
Multicentre interventional double-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Efficacy, Quality of life, Safety, Treatment

Health condition(s) or problem(s) studied
Treatment of abdominal pain in children and young people with Functional abdominal pain disorders.

Interventions

The intervention is Enterosgel® an intestinal adsorbent classified as a medical device class IIA since 2011 in Europe. Currently indicated for symptomatic treatment of acute diarrhoea and irritable bowel syndrome with diarrhoea (IBS-D), available and an OTC and on prescription in the UK.

Enterosgel® is a tasteless gel that is mixed in water and taken orally. The dose is age dependent as per the Instructions for use.

During the double-blind phase (4 weeks) patients will be randomised 1:1 to receive Enterosgel® or placebo, pre-mixed in water and dispensed in tubes ready to drink. During the open label phase Enterosgel® will be dispensed in tubes as a gel, ready to measure and then mix in water. This is followed by the 4 week open label phase for all participants allocated Enterosgel intervention. At the end of this phase participants return to standard care.

Randomisation will be using a computer-based randomisation tool (Red Pill) within the eCRF (Sealed Envelope Ltd, UK), accessible once the eligibility criteria are confirmed.

Intervention Type
Device

Phase
Phase II/III

Drug/device/biological/vaccine name(s)
Enterosgel®

Primary outcome(s)
Comparison of the change in mean daily Wong-Baker FACES Pain Rating Scale (limited to abdominal pain) during weeks 1-2 (initial observation phase) and the double-blind phase (week 3-6) recorded in the daily diary in the Enterosgel® versus the placebo arm

Key secondary outcome(s))
Comparison of the Enterosgel® versus the placebo arm during the double-blind treatment phase and open-label treatment phase:
1. mean daily Wong-Baker FACES Pain Rating Scale recorded in the daily diary
2. The proportion of days with any abdominal pain
3. The proportion of days missed nursery/school
4. Change in the Stomach Pain and Hurt total score (comprised of 6 items) of the PedsQL 3.0 GIS module (parent/carer proxy-report for 3-4-year-olds and child self-report from 5-18 years; by parent/carer proxy-report for 3-18-year-olds)
5. Change in other individual components of the PedsQL 3.0 GIS module (parent/carer proxy-report for 3-4-year-olds and child self-report from 5-18 years; by parent/carer proxy-report for 3-18 years olds): stomach discomfort when eating (5 items), food and drink limits (6), trouble swallowing (3), heartburn and reflux (4), nausea and vomiting (4), gas and bloating (7), constipation (14), blood in bowel movement (2), diarrhoea (7), worry about bowel movements (5), medicines (4), communication (5).
6. Change in total PedsQL 3.0 GIS module score (parent/carer proxy-report for 3-4-year-olds and child self-report from 5-18 years; by parent/carer proxy-report for 3-18 years olds)
7. Change in health-related quality of life KIDSCREEN-27 questionnaire for children 8-18 years

(child report and parent/carer proxy-report)
8. Acceptability of the study interventions (daily diary)
9. Adverse Events

Completion date
01/02/2027

Eligibility

Key inclusion criteria
1. Written informed consent
2. Children aged 3-18 years (parent/carer available to provide proxy-report and/or parent/carer report) with a clinical diagnosis of FAPD (Group H2) according to the Rome IV criteria
3. Normal faecal calprotectin at FAPD diagnosis (≤250 ug/g stool age 3-8 yrs, ≤100 ug/g stool age 9-18 yrs)
4. Considered suitable to take part in the study by the consenting investigator
5. Diary completed on at least 11 days (≥75%) during the observational period
6. Able to complete questionnaires in English
7. Able to complete e-diary and questionnaires on-line

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
3 years

Upper age limit
18 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Previously diagnosed coeliac disease, inflammatory bowel disease or other significant gastro-intestinal disorder
2. Average number of stools per week <3
3. Previous use of Enterosgel®
4. Use of antidepressant agents, unless used at a stable dose for at least 6 weeks
5. Use of any probiotic supplements, other intestinal adsorbents, slow-release medications or strong opioids
6. Participation in any research where treatment is provided in the last three months

7. Pregnancy or not willing to use contraception for the duration of the study in females of childbearing potential defined as any female over 11 years of age and who has not undergone surgical sterilization (hysterectomy or bilateral oophorectomy) or is not postmenopausal

Date of first enrolment
01/01/2026

Date of final enrolment
31/10/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Alder Hey Children's NHS Foundation Trust
Eaton Road
Liverpool,
England
L12 2AP

Study participating centre
Bristol Royal Hospital for Children
Upper Maudlin Street
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Sponsor information

Organisation
Enteromed Ltd

Funder(s)

Funder type
Industry

Funder Name
Bioline Products s.r.o.

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available on request from Dr Carol Howell email; research@enteromed.co.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1.0	07/05/2025	19/05/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes