

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

Submission date 07/04/2025	Recruitment status Not yet recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 21/05/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 01/07/2025	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

356725

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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)

Not yet submitted, Ethics committee name not provided (Address not provided, City not provided, Zip/postal code not provided; Telephone number not provided), ref: Reference number not provided

Study design

Multicentre interventional double-blinded randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital, Internet/virtual

Study type(s)

Quality of life, Treatment, Safety, Efficacy

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

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 as 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

Pharmaceutical study type(s)

Dose response

Phase

Phase II/III

Drug/device/biological/vaccine name(s)

Enterosgel®

Primary outcome measure

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

Secondary outcome measures

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

Overall study start date

08/04/2025

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 ($\geq 75\%$) 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

Age group

Child

Lower age limit

3 Years

Upper age limit

18 Years

Sex

Both

Target number of participants

154

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

01/09/2025

Date of final enrolment

31/08/2026

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Alder Hey Children's NHS Foundation Trust

Eaton Road

Liverpool,

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Study participating centre

Bristol Royal Hospital for Children

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Sponsor information

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Sponsor type

Industry

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Funder(s)

Funder type

Industry

Funder Name

Bioline Products s.r.o.

Results and Publications

Publication and dissemination plan

Planned publication in peer-reviewed journal

Intention to publish date

01/04/2027

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?
Protocol file	version 1.0	07/05/2025	19/05/2025	No	No