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

Submission date	Not yet recruiting	[X] Prospectively registered		
07/04/2025		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
21/05/2025	Ongoing  Condition category  Digestive System	☐ Results		
Last Edited		Individual participant data		
12/11/2025		[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

#### Contact name

Dr Carol Howell

#### **ORCID ID**

https://orcid.org/0000-0001-5713-6177

#### Contact details

Enteromed Ltd, 85 Great Portland St, First Floor London United Kingdom W1W 7LT +447596887046 research@enteromed.co.uk

## Type(s)

Principal investigator

#### Contact name

Prof Stephen Allen

#### ORCID ID

https://orcid.org/0000-0001-6675-249X

#### Contact details

Department of Clinical Sciences, Liverpool School of Tropical Medicine Liverpool United Kingdom L3 5QA +44 7584 200611 stephen.allen@lstmed.ac.uk

# 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 proxyreport 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 Enterosael®
- 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
Bristol
England
BS2 8BJ

# 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			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