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Treating IBS with an Intestinal Microbiota Product for Health - TrIuMPH

Submission date 05/12/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 10/04/2025	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 10/04/2025	**Condition category** Digestive System	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

The study aims to assess the safety and efficacy of EBX-102-02 in patients with constipation-predominant Irritable bowel syndrome (IBS-C) and diarrhea-predominant irritable bowel syndrome (IBS-D). IBS is a common condition that affects the digestive system. It causes symptoms like stomach cramps, bloating, diarrhoea and constipation. These tend to come and go over time and can last for days, weeks or months at a time. It's usually a lifelong problem. It can be very frustrating to live with and can have a big impact on everyday life. The exact cause is unknown. Current treatments focus on relieving the symptoms. There is increased interest in the microbiota of IBS and EBX-102 has the potential to improve microbial diversity. EBX-102 capsules contain communities of dried, intestinal microorganisms taken from carefully screened pooled human stool samples.

Who can participate?

Patients aged ≥18 years up to 70 years old with a clinical diagnosis of IBS-C

What does the study involve?

The study will be conducted in 2 centres - The functional Gut Clinics, based in Manchester and London. 120 participants randomised in a 2:1 ratio (60 participants for the IBS-C and 60 for the IBS-D cohort with approximately 40 in the active and 20 in the placebo group for each cohort, respectively). Once eligibility criteria are confirmed and written informed consent has been obtained, participants will undergo at least a 2-week screening period to confirm the diagnosis of IBS-C. Once randomisation occurs, 8 capsules of the study drug will be administered on day 1 and day 8. Participants will then be followed up for 6 weeks (after the last dose of the study drug). The total period of study for an individual participant will be approximately 9 weeks (2 weeks screening, 1 week treatment, 6 weeks follow-up). The following assessment information will be performed/collected - medical history, physical exam, vital signs, ECG, blood sampling, stool collection, completion of questionnaires, patient diary, concomitant medication, demographics and breath tests.

What are the possible benefits and risks of participating?
There are risks, discomforts, and inconveniences associated with any research study. It is possible that these general risks could be increased by the addition of test medications. Some of the general risks may be potentially life-threatening and may not have been previously reported.

Study Assessment Risks:
Some of these procedures take place more often than they would if patients were not taking part in this study.

Blood Collection:
Taking blood samples may cause bruising and discomfort and a risk of infection or blood clots at the site of the blood collection.

Study Treatment:
Will be given in a clinic with emergency equipment and staff who are trained to monitor for and respond to any potential medical emergencies.

Risks Associated with EBX-102-02 :
Stomach pain and other gastro-type symptoms after taking the capsules. The known side effects of this type of treatment typically include bloating, diarrhoea and stomach cramps. These symptoms do not occur in everybody who takes them. Participants are encouraged to inform their study team about any side effects that they experience. The study doctor may provide additional medications to ease the experience of side effects; however, typically, symptoms resolve within a few days.

Risk of exposure to pathogens contained in the IMP due to the nature of intestinal microbial ecosystems. The sponsor operates a robust biosafety programme focussed on ensuring that starting material is appropriately and extensively screened, rendering it safe for its intended use. The sponsor works with a small number of accredited and audited laboratory partners as well as utilising in-house pathogen screening capabilities that include state-of-the-art technology. Regular monitoring of safety data for indications that pathogens have been transmitted.

Unknown Risks:
Side effects of EBX-102-02, which are unknown at this time, may occur during the study. Any new information that may affect participants' health or which may make the participants want to stop taking part in the study will be shared with them as soon as it becomes available.

Pregnancy Prevention:
There may be a risk in exposing an unborn child to study drugs, and all risks are not known at this time. Women must take precautions to avoid exposing an unborn child to study drugs, as described in the PIS-ICF.

Patients will be informed of all of the above risks in the Patient Information Sheet and will be asked to notify their study doctor or study staff should they experience any side effects during the study. Patients will be monitored throughout the study to minimise risks.

Where is the study run from?
EnteroBiotix Ltd

When is the study starting and how long is it expected to run for?
December 2023 to December 2024

Who is funding the study?
EnteroBiotix Ltd

Who is the main contact?
Shinofa Rizan, clinops@enterobiotix.com

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1009182

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
EBX-102-02-201, IRAS 1009182

Study information

Scientific Title
A randomised, double-blind, placebo-controlled, phase II trial assessing the safety and efficacy of EBX-102-02 in patients with Irritable Bowel Syndrome (IBS)

Acronym
TrIuMPH

Study objectives
To assess the safety and tolerability of EBX 102-02 in irritable bowel syndrome participants

To assess the effects of EBX-102-02 on:
IBS-C symptomatology including:
Pain
Bloating
Stool consistency and frequency

Biomarker breath test measurements

Intestinal microbiome composition

Quality of life/global well-being

Anxiety and depression

Stool based short chain fatty acids (SCFAs) and bile acids (BAs)

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 23/01/2024, West Midlands - Edgbaston Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)20 7104 8155 ; edgbaston.rec@hra.nhs.uk), ref: 23/WM/0274

Study design
Randomized double-blind placebo-controlled phase II trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Safety, Efficacy

Participant information sheet

Health condition(s) or problem(s) studied
Irritable bowel syndrome (IBS)

Interventions
EBX-102-02 is a gastro-resistant hard hydroxypropyl methylcellulose (HPMC) capsule containing communities of dried, intestinal microorganisms derived from rigorously screened pooled human stool samples. Visual and weight-matched placebo capsules are available to maintain the blind. Participants will be randomly assigned in a 2:1 ratio to receive active or placebo IMP via an Interactive Web-based Randomisation System.
Participants will receive 8 capsules of IMP to be taken at each of 2 separate administrations 1 week apart. Administrations will be directly observed in the clinic. Participants will then be followed up for 6 weeks (after the last dose of IMP).

Intervention Type
Drug

Pharmaceutical study type(s)
Not Applicable

Phase
Phase II

Drug/device/biological/vaccine name(s)
EBX-102-02 [EBX-102]

Primary outcome measure
Incidence of adverse events (AEs) and safety data (including vital signs, physical examinations and laboratory test results) up to and including 6 weeks post-treatment

Secondary outcome measures
The following secondary outcome measures will be assessed up to and including 6 weeks post-treatment:
1. Change in IBS-C symptomatology measured on the IBS Symptom Severity Score (IBS-SSS).
2. Change in responses to Patient Assessment of Constipation Symptoms (PAC-SYM) questionnaire
3. Change in stool consistency measured on the Bristol Stool Scale
4. Change in stool frequency and other symptomatology measured by a bowel habit diary
5. Change in fermentation profiles, total gas production, and small intestinal bacterial overgrowth in biomarker breath test measurements
6. Taxonomic microbiome analysis
7. Change in Quality of Life scores measured on the IBS Quality of Life questionnaire (IBS-QOL)
8. Change in Hospital Anxiety and Depression score
9. Requirement for rescue medication
10. Metabolite analysis: SCFAs and BAs in stool

Overall study start date
01/12/2023

Completion date
23/12/2024

Eligibility

Key inclusion criteria
1. Willing and able to provide informed consent
2. Male or female aged ≥ 18 years up to 70 years
3. A clinical diagnosis of IBS-C or IBS-D, as confirmed by Rome IV grading criteria, excluding patients with mild disease by using an IBS-SSS inclusion of ≥ 175
4. Willing to discontinue all medications for bowel habit abnormalities after providing consent
5. Willing to abstain from consuming regular 'over-the-counter' pre- or probiotics from pharmacies or other retailers from screening through to end of follow-up
6. If women of childbearing potential (WOCBP), subjects must have a negative serum pregnancy test at screening, a negative urine pregnancy test at randomisation and must be willing to use a highly effective method of birth control for the duration of the study. Acceptable methods of contraception:
6.1. Hormonal contraception associated with inhibition of ovulation
6.2. Intrauterine device (IUD)
6.3. Intrauterine hormone-releasing system (IUS)
6.4. Bilateral tubal occlusion
6.5. Vasectomised partner
6.6. Sexual abstinence, in line with the preferred and usual lifestyle of the subject
Note: Periodic abstinence (such as calendar, ovulation, symptothermal, post-ovulation methods) and withdrawal, and condom with spermicide, are not considered a highly effective method of contraception for female subjects of childbearing potential.
7. If male, subjects must be prepared to use reliable barrier method contraception and a second method such as spermicide for the duration of the study unless surgically sterile

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
120

Key exclusion criteria
1. Women who are pregnant or breastfeeding
2. Planned surgery requiring general anaesthetic during the course of the study
3. Participants who are planning to significantly change their diet (e.g. weight loss programme, becoming vegetarian) during the study period. Patients established on a low fermentable oligosaccharides, disaccharides, monosaccharides and polyols (FODMAP) diet can continue without changes to it
4. Confirmed diagnosis of mixed type IBS (IBS-M), or unclassified IBS (IBS-U)
5. In IBS-C subjects: diarrhoea within 7 days prior to screening
5.1. If possible infective diarrhoea, then wait 3 weeks before starting bowel habit diary
6. In IBS-D subjects
6.1. Nocturnal diarrhoea
6.2. BSS type 7 on more than 5 days per week
6.3. Diarrhoea associated with foreign travel in the 4 weeks prior to screening
7. Other chronic gastrointestinal (GI) disease including:
7.1. Inflammatory bowel disease
7.2. Diverticulitis
7.3. Malabsorption syndromes e.g. lactose intolerance (with proven lactase deficiency)
8. Any history of malignant tumours (primary or secondary) affecting any part of the GI tract
9. History of colectomy/ileostomy at any time
10. History of colonic perforation or fistula
11. History of any malignancy within the 5 years prior to screening, excluding non-melanoma skin cancers
12. Conditions associated with increased risk of GI cancer, e.g. familial adenomatous polyposis coli
13. Abdominal surgical intervention except for appendectomy, hernia repair, and gynaecological and urological procedures
14. Known lactulose intolerance
15. Ongoing requirement for medications known to cause constipation e.g. Iron supplementation, opiates or diarrhoea e.g. antacids, non-steroidal anti-inflammatory drugs (NSAIDs)
16. Use of any prohibited medications for which a participant cannot complete the appropriate washout period
17. Aspartate aminotransferase (AST) or alanine aminotransferase (ALT) ≥ 2.5x upper limit of normal (ULN)
18. History of human immunodeficiency virus (HIV), hepatitis B virus (HBV) or hepatitis C virus

(HCV) infection, regardless of current viral status and test results
19. Use of systemic antibiotics within 7 days prior to screening, or intended use during the study
20. Faecal microbiota transplantation (FMT) within the past 12 months
21. History of sensitivity to any of the study drug components, or a history of drug allergy that in the opinion of the Investigator contraindicates study participation
22. Participants with dysphagia, or inability to ingest capsules (e.g. severe nausea, vomiting, delayed gastric emptying) or history of 'choking' on capsules
23. Have taken an IMP within the last 3 months
24. Planned or active participation in any other study with an IMP
25. Any autoimmune or oncologic disease requiring, or that may require, systemic treatment with steroids and/or other immunosuppressants/immunomodulators
26. Significant bleeding disorder
27. Anaphylactic food allergy
28. Requirement for vasopressors
29. Valvular heart disease or known structural defects of the heart
30. Clinically significant medical or surgical history or any condition that could interfere with study participation or confound the assessments in the opinion of the study Investigator

Date of first enrolment
11/03/2024

Date of final enrolment
11/11/2024

Locations

Countries of recruitment
United Kingdom

Study participating centre
-
United Kingdom
-

Sponsor information

Organisation
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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
EnteroBiotix Ltd

Results and Publications

Publication and dissemination plan
1. Peer reviewed scientific journals
2. Internal report
3. Conference presentation
4. Publication on website
Following completion of the study, the results will be reported publicly. The Sponsor intends to publish the results of the clinical study consistent with the Declaration of Helsinki (2013). All participant data will be published in aggregate and no single participant will be identified.

Intention to publish date
30/09/2025

Individual participant data (IPD) sharing plan
The data sharing plans for the study are unknown at this time and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date