EnteroBiotix thanks all patients who volunteered for this study, as well as their families and carers for their support.

Study title, who, where and when:

TrIuMPH - Treating irritable bowel syndrome (IBS) with an Intestinal Microbiota Product for Health

This study was carried out by the company EnteroBiotix, which is developing the medicine EBX-102-02. The study started in March 2024 and ended December 2024. Doctors and research teams conducted the study at two clinics in the UK which have a special interest in looking after patients with irritable bowel syndrome. These clinics received funding from EnteroBiotix to cover the costs of treatment, tests, and study procedures.

Why was the research needed?

Irritable bowel syndrome (IBS) is a common condition that affects the bowels. It causes pain (such as stomach cramps, bloating or general discomfort in the belly), and changes the speed at which food is digested and passes through the gut. When digestion is too fast, this causes diarrhoea - loose or watery stools and frequent trips to the toilet. When too slow, stools become hard and difficult to pass (constipation), and a person may go several days without being able to empty their bowels. These symptoms tend to come and go over time, and can last for days, weeks or months. IBS is usually a lifelong condition. It can be very frustrating to live with and can have a big impact on everyday life. Current treatments focus on relieving the symptoms.

The exact cause of IBS is unknown, but research suggests that the micro-organisms (gut bugs) which live in everyone's gut may become out of balance in people with IBS, and this may be a major part of the problem. If so, restoring a healthier mix of gut bugs may help improve symptoms. EBX-102-02 is a new treatment that aims to do this. It is made by carefully preparing healthy gut bugs collected from screened UK volunteer donors, and every batch is extensively tested for safety. EBX-102-02 is supplied as an odourless, colourless powder inside a capsule, which is swallowed by the patient. The capsule is designed to stay intact as it passes through the stomach and only breaks down once it reaches the intestines - releasing the healthy gut bugs where they are needed, so they can begin to grow.

What were the main questions studied, who participated and what treatments were taken?

The study aimed to find out whether EBX-102-02 was safe for people with irritable bowel syndrome, and whether it could successfully change the mix of gut bugs in patients.

Two types of patients with IBS were studied. Either patients whose bowel habit was mostly constipation, or those with mostly diarrhoea.

Patients were randomly assigned to either have a treatment with EBX-102-02, or to get a dummy pill which contained no gut bugs. For every patient who was given the dummy pill, two patients were given the EBX-102-02 treatment containing the healthy bugs.

Treatment was given in the clinic on the first day of study as a single dose, with a second dose given in clinic one week later.

First, the study wanted to find out whether EBX-102-02 could be given to people with IBS without causing concerning side effects.

Second, the study looked at whether EBX-102-02 improved the severity of symptoms, using a specific IBS questionnaire and a daily diary which patients completed throughout the study.

What medical problems (adverse reactions) did the participants have?

Most medical problems were mild and lasted a short time, resolving without needing further treatment. These mainly involved discomfort in the belly, feeling sick (nausea), or changes in how often patients went to the toilet. One patient stopped treatment after the first dose because of being sick. No problems required patients to be admitted to hospital.

What happened during the study and what were the results?

One hundred and twenty-two patients were studied; 80 patients received treatment with EBX-102-02 and 42 were given the dummy pills.

The study showed that, in both IBS with constipation and IBS with diarrhoea, treatment with EBX-102-02 reduced the severity of symptoms by a greater amount than the dummy pill. This difference was seen early in the study, from week 1, and continued throughout the full seven weeks.

Patients who received EBX-102-02, in both IBS-constipation and IBS-diarrhoea, reported less severe pain during the study, compared to those receiving the dummy pill.

Patients with IBS-constipation generally had fewer constipated days, fewer days where their stool was hard and difficult to pass, and more days where their stool was normal.

Patients with IBS-diarrhoea generally had fewer days where their stool was loose or watery.