CLINICAL RESEARCH CASE STUDY
IBS Research and Probiotics

Assessing the impact of a probiotic combo on mood, stress and bowel symptoms in adults with Irritable Bowel Syndrome

Presented by:

atlantia
clinical trials

Executive Summary

Irritable bowel syndrome (IBS) is characterized by chronic abdominal pain, discomfort, bloating, and alteration of bowel habits and affects 10-15% of the general population.

In this work, we utilised two well-characterised strains. Each strain has interesting properties related to IBS. The first one has been shown to attenuate the anxiety and stress and improving cognition in preclinical and clinical studies. The second strain has been extensively studied and shown to regulate inflammatory responses and reduce abdominal pain, bloating, gas and unpredictable bowel habits in IBS subjects in two well-controlled clinical studies. Therefore, the aim of this trial is to investigate the effect of a combination of both on bowel symptoms and stress/mood in adults with IBS. The research project consisted of 2 phases: 1) a pilot study and 2) a randomized, double-blind, placebo-controlled crossover study.

Atlantia first performed a pilot study to estimate the carryover effect and determine the washout period required for the randomized, double-blind, placebo-controlled crossover study and provide preliminary data on the subject characteristics and variation in the parameters measured.

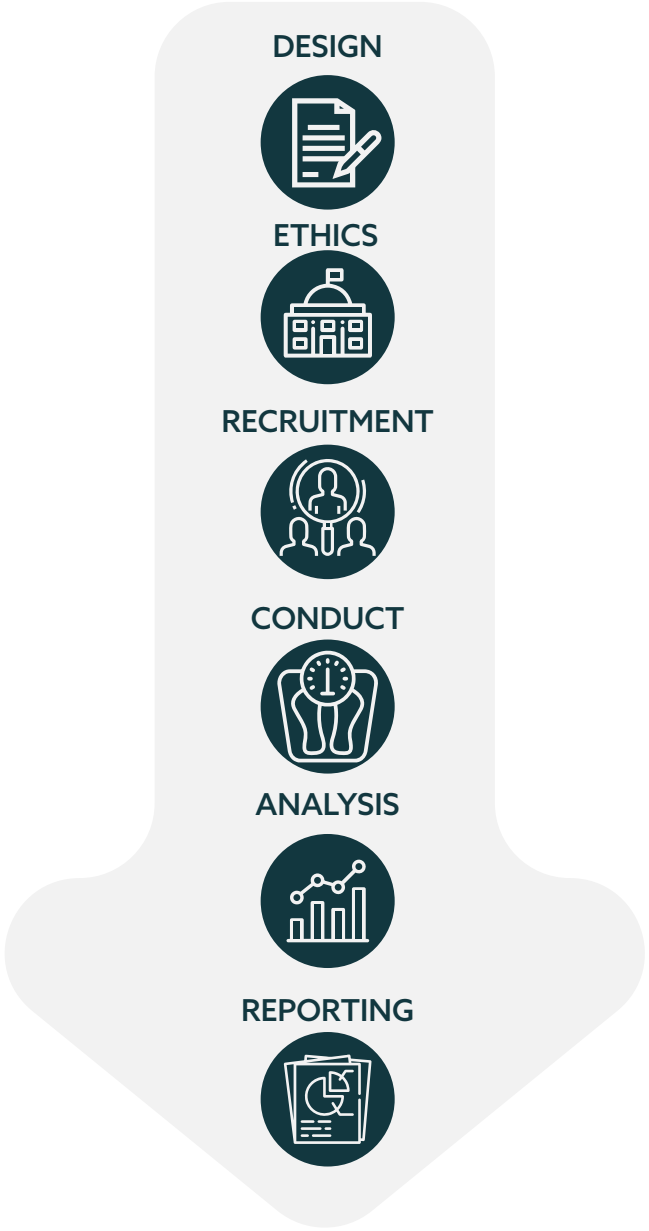
Challenges and Objectives

The primary objective was to assess the impact of the investigational product on stress and mood in adults with IBS as determined by change in HADs score.

Other objectives were to assess the impact of the investigational product on IBS symptoms, on abdominal pain/discomfort, and on individual symptoms such as Stool frequency, Stool consistency (Bristol Stool Scale), Abdominal pain/discomfort, Abdominal bloating/distension, Bowel movement urgency, Straining and Passage of gas.

The safety of the investigational product was evaluated throughout the study on the basis of serious and non-serious adverse events and safety parameters.

The main challenge was to ensure that an intervention from one period did not have a residual effect that persisted into the subsequent period in a cross-over design. This is called a carryover effect. A technical team with the expertise on these type of designs was required.



How Atlantia's Solution Helped

Atlantia's world-class team of doctors, scientist, nutritionists, and research nurses worked closely with the Sponsors' researchers to design and deliver the study objectives. Atlantia's expert team in stress and anxiety was a perfect fit for the sponsors research needs.

A crossover study design was recommended by our expert team. Each participant served as his/her own control and both interventions (the investigational product and Placebo) were evaluated for the same individual. This allowed the same precision as a parallel group trial with only half the sample size.

About the Study

The underlying factors contributing to IBS are heterogeneous and not completely understood but it is considered that altered gut mucosal immune activation cognitive function, psychological stress, brain-gut interaction and changes in the gut microbiota are significant contributors to the condition.

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In both the pilot and crossover study, we measured stress and mood using validated questionnaires aand other biological biomarkers. Bowel symptoms were measured using self-reported measures of abdominal pain, passage of gas, stool form and consistency as well as straining and bowel movement urgency on a daily basis using an eDiary system. Other measures will include weekly global assessment of IBS symptoms and abdominal pain/discomfort.

eDiary app example

Subjects were recruited through our database, General Practitioners offices and posting adverts in local newspapers. Subjects underwent an initial phone screen and were asked questions regarding their age, gastrointestinal symptoms, history of mood and stress and previous and current medications. Eligible subjects were scheduled for a screening visit.
The study was conducted as outlined in the protocol and in accordance with the ICH Guidelines on Good Clinical Practice, and the declaration of Helsinki.

The pilot study was an open label design as outlined below. All volunteers took the investigational product for 8-weeks, followed by an 8-week follow up. Volunteers were screened according to the selection criteria. Subjects were screened in order to identify up to participants, between 18 and 55 years of age, with recurrent abdominal pain/discomfort and mild to moderate stress/mood status. The study involved visits over a 20-week period.
A blood sample was collected at each visit. A urine sample was collected at the screening and baseline visits and upon completion of the intervention. For women of childbearing age, a pregnancy test were performed.
A saliva sample was collected on the morning of each visit. Subjects were instructed to avoid brushing teeth or using mouth wash on the morning of the saliva collection. Subjects were provided with a stool collection kit at visits and instructed to collect a sample at home and bring it to the clinic at their next visit.

Stool samples were stored at –80°C and analysed for presence/absence of the probiotic strains as an indicator of transit/washout of the probiotic strains and stored for microbiota diversity analysis, compositional analysis, SCFA analysis and metabolomics.
The second study was a randomized, double blinded, placebo-controlled study using a repeated measures cross-over design as outlined below.

Volunteers were screened according to the selection criteria. Participants were, between 18 and 55 years of age with IBS experiencing recurrent abdominal pain/discomfort and mild to moderate stress/mood status. The study involved visits over a 28-week period.

The volunteers were randomised to Group 1 or Group 2 and underwent a 8-week intervention with either the investigational product or matching Placebo with a washout period between interventions.
Further urine, saliva, blood and faecal samples were collected during the crossover study to assess similar endpoints in the pilot study.

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Discuss your research program with our clinical trial experts:

Email us at sales@atlantiatrials.com

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