ClinicalTrials.gov PRS
Protocol Registration and Results System

ID: IBS-2 Effect of Probiotic Supplement in Alleviating Functional Gastrointestinal Symptoms NCT01728610

Protocol Registration Preview

Effect of Probiotic Supplement in Alleviating Functional Gastrointestinal Symptoms

This study has been completed.

Sponsor:
Danisco

Information provided by (Responsible Party):
Danisco

ClinicalTrials.gov Identifier:
NCT01728610

First received: October 5, 2012
Last updated: January 25, 2016
Last verified: January 2016

Purpose

The purpose of this study is to analyse the effect of a probiotic supplement on functional intestinal symptoms among subjects diagnosed with irritable bowel syndrome (IBS).

Condition	Intervention	Phase
Irritable Bowel Syndrome	Dietary Supplement: Probiotic (Active high) Dietary Supplement: Probiotic (Active low) Dietary Supplement: Placebo	Phase 2

Study Type: Interventional
Study Design: Supportive Care, Parallel Assignment, Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor), Randomized, Safety/Efficacy Study

Official Title: Effect of Probiotic Supplement in Alleviating Functional Gastrointestinal Symptoms (IBS-2)

Further study details as provided by Danisco:

Primary Outcome Measure:

- Change in functional bowel symptoms [Time Frame: 0 weeks, 4 weeks, 12 weeks] [Designated as safety issue: No]
  Validated questionnaire

Secondary Outcome Measures:

- Change in quality of life [Time Frame: 0 weeks, 4 weeks, 12 weeks] [Designated as safety issue: No]
  Validated questionnaire

- Change in anxiety and depression [Time Frame: 0 weeks, 4 weeks and 12 weeks] [Designated as safety issue: No]
  Validated questionnaire

- Adequate relief [Time Frame: Weekly over 3 month intervention] [Designated as safety issue: No]
  Weekly question

- Change in faecal microbiota [Time Frame: 0 weeks, 4 weeks, 12 weeks] [Designated as safety issue: No]
  Detection and quantification of microbes from faecal samples

- Safety of investigational product [Time Frame: Throughout the intervention phase] [Designated as safety issue: Yes]
  Recording of adverse events and serious adverse events

Enrollment: 391
Study Start Date: October 2012
Study Completion Date: November 2014
Primary Completion Date: November 2014

Arms	Assigned Interventions
Active Comparator: Active high Probiotic, high dose	Dietary Supplement: Probiotic (Active high) Higher dose of probiotic supplement Other Names: • Lactobacillus
Active Comparator: Active low Probiotic, low dose	Dietary Supplement: Probiotic (Active low) Lower dose of probiotic supplement Other Names: • Lactobacillus
Placebo Comparator: Placebo Placebo	Dietary Supplement: Placebo Placebo Other Names: • Maltodextrin as placebo

The aim of the intervention is to analyse the effect of a probiotic supplement in a dose-responsive set up on functional intestinal symptoms among subjects

diagnosed with IBS according to Rome III criteria. Subjective assessment of bowel symptoms, quality of life, anxiety and depression and adequate relief will be assessed as with questionnaires as outcome measures. The intestinal microbiota will be analysed from faecal samples.

Eligibility

Ages Eligible for Study: 18 Years to 65 Years
Genders Eligible for Study: Both
Accepts healthy volunteers.
Inclusion Criteria:

- Subjects aged 18 to 65 fulfilling Rome III criteria for IBS will be recruited. Sufficient general health and orientation for participating in the study is required and will be evaluated by the MDs.

Exclusion Criteria:

- Diagnosed or suspected organic gastrointestinal diseases or severely impaired general health.

Contacts and Locations

Locations

Finland

Mehiläinen Töölö
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Turku, Turku, Finland, 20100

Investigators

Principal Investigator:	Lea Veijola, MD	Herttoniemi Hospital
Study Chair:	Arthur Ouwehand, PhD	DuPont Nutrition and Health
Study Chair:	Sampo Lahtinen, PhD	DuPont Nutrition and Health
Study Director:	Anna Lyra, PhD	DuPont Nutrition and Health

More Information

Responsible Party:	Danisco
Study ID Numbers:	IBS-2
Health Authority:	Finland: Ethics Committee
Plan to Share Data?:	No
Study Data/Documents:	Summary - Conclusions Efficacy Results: IBS symptoms were significantly alleviated during the study in all three treatment groups with no statistically significant difference between the placebo and active groups. The

secondary outcome measures were not affected by the treatment.

In a post-hoc analysis for a subgroup of subjects suffering from moderate to severe abdominal pain at baseline, the active treatment reduced abdominal pain during the intervention.