The effect of Lactobacillus plantarum 299v on symptoms and intestinal flora in patients with irritable bowel syndrome (IBS)

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The efficacy and safety of Lactobacillus plantarum 299v in patients with IBS will be investigated in a double-blind, randomised, placebo-controlled study. The Sponsor has earlier got an approved health claim in Sweden for gut health and intake of...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal disorders
Study type	Interventional

Summary

ID

NL-OMON41453

Source
ToetsingOnline

Brief title
PRO008

Condition

- Gastrointestinal disorders

Synonym
Irritable Bowel Syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Probi A

Source(s) of monetary or material Support: Probi AB (sponsor of this study ;see B7)

Intervention

Keyword: Abdominal pain, Flatulence, Irritable bowel syndrome (IBS), Lactic acid bacteria

Outcome measures

Primary outcome

The primary object is to determine the effect of Lactobacillus plantarum 299v on abdominal pain over 4 weeks of consumption in comparison to placebo in IBS out-patients determined with pain nummeric rating scale (NRS). The primary efficacy endpoint ischange from baseline in abdominal pain NRS after 4 weeks.

Secondary outcome

- The effect of Lactobacillus plantarum 299v on the total scores of IBS severity scoring system (IBS-SSS) over 4 weeks consumption with placebo in IBS out-patients
- The effect of Lactobacillus plantarum 299v on flatulence over 4 weeks consumption in comparison with placebo in IBS out-patients determined with a flatulence scale
- The effects of Lactobacillus plantarum 299v on bloating over 4 weeks consumption in comparison with placebo in IBS out-patients determined with IBS-SSS
- The effects of Lactobacillus plantarum 299v on stool form and frequency according to the Bristol stool form (BSF) over 4 weeks consumption in comparison with placebo in IBS out-patients
- The effects of Lactobacillus plantarum 299v on faecal microflora after 4 weeks consumption in comparisons with placebo

- The effects of Lactobacillus plantarum 299v on gastrointestinal (GI)

wellbeing/comfort after 4 weeks consumption in comparison with placebo

-The effects of Lactobacillus plantarum 299v on global efficacy after 4 weeks

consumption in comparison with placebo

- The frequency of Adverse Events collected during the study

Study description

Background summary

Irrirable Bowel Syndrome (IBS) is a complex condition with variable symptomatology involving mucosal integrity and function, gut function, visceral perception and brain-gut dysregulation. Although IBS is a multi-symptom disorder abdominal pain or discomfort is its definitive characteristic and is a predominant feature of the IBS illness experience. Abdominal pain independently drives health related quality of life decrements in IBS and is the principal driver of patient reported symptom severity.
Lactobacillus plantarum 299v has in previous studies been shown to decrease pain and flatulence in patients with IBS. The studies were double blind and placebo controlled. Patients with IBS were given a diet supplement or a fruit drink with or without Lactobacillus plantarum 299v and IBS-symptoms were followed during 4 weeks.
Lactobacillus plantarum is often present in the human gut as well as in many types of food such as fermented vegetables, yoghurt, cheese and berries.

Study objective

The efficacy and safety of Lactobacillus plantarum 299v in patients with IBS will be investigated in a double-blind, randomised, placebo-controlled study. The Sponsor has earlier got an approved health claim in Sweden for gut health and intake of Lactobacillus plantarum 299v based on three human trials (Johansson et al. 1998, Nobaek et al. 2000, Niedzielin et al. 2001). However, since July 1, 2007, health claims made in relation to food products require authorisation under Regulation EC 1924/2006 before they can be used in the labelling and marketing of these products in the EU. These three references were therefore sent in for evaluation of a health claim pursuant article 13.1 of regulation no 1924/2006 but a negative opinion was published (EFSA Journal 2011:9(4):2037). According to the opinion the evaluated studies had some different shortcomings such as insufficient control for other substances besides Lactobacillus plantarum 299v and unsatisfactory information about the

validity of the used scales. Since then one further study with positive results has been done (Ducrotté et al. 2012) but recently one study with non-significant results was finished in Denmark. To be able to have an approved health claim in EU it is therefore need to perform at least one more study showing positive results.
The safety of these lactic acid bacteria has also been proven by many years of use in food and in clinical trials. Therefore, one may also assume a good benefit/risk ratio for this nutrional study.

Study design

The study is a randomised, placebo-controlled, double-blind, parallel, single centre intervention study with IBS out-patients. A total of 200 male and female patients with IBS are planned to be randomised at 1 site in The Netherlands. Patients with IBS according to the Rome III criteria can be considered for participation in this study. The patient will receive information about the study and after a screening visit and a 2 week run-in period patients with abdominal pain score between 3-6 on a 0-10 point Linkert scale with a frequency of at least two days a week will subsequently be randomised to receive either Lactobacillus plantarum 299v or placebo capsules for 4 weeks.
A total of 385 patients are planned to be enrolled and 200 patients are planned to be randomised with 100 patients each arm. The total duration for the patient in the study will be 6 weeks.

Intervention

Capsules with Lactobacillus plantarum 299v or placebo

Study burden and risks

A benefical effect of Lactobacillus plantarum 299v on gastrointestinal health has already been found in clinical trials. The safety of these lactic acid bacteria has also been proven by many years of use in food and in clinical trials. Therefore, one may also assume a good benefit/risk ratio for this nutrional study.
By taking part in this study, the patient will receive extra attention for and insight in his/her health problem. For this the patient will have to visit the centre for 3 visits, have to complete questionnaires, keep a diary (by telephone), undergo vital signs measurement , withhold from the use of probiotic products or drugs (interfering with study evaluation) for 4-6 weeks, use of antibiotics for 8-10 weeks. Furthermore, samples of the faeces and one bloodsample will be collected.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Willing and able to provide informed consent
- Age *18 and * 70 years at Visit 1
- IBS according to the Rome III criteria
- A score on abdominal pain NRS * 3 and * 6 at least two days a week measured the weeks before Visit 2 (baseline)
- IBS-SSS * 75 and * 300 at Visit 2 (baseline)
- Ability and willingness to understand and comply with the study procedures

Exclusion criteria

- Known intolerance or allergy to milk products (protein or lactose) or gluten

- History of alcohol or substance abuse six months prior to screening
- Known Hepatitis B or C Human Immunodeficiency Virus (HIV) 1 or 2
- Female patients: currently pregnant or breast-feeding or intending to become pregnant during the study
- Abnormal results of the screening laboratory tests clinicallly relevant for study participation, as judged by the Investigator
- Other gastrointestinal disease(s) that explains the patient's symptoms, as judged by the Investigator
- Other severe disease(s) such as malignancy, severe coronary disease, kidney disease or neurological disease, as judged by the Investigator
- Symptoms indicating other severe disease(s) such as gastrointestinal bleeding, loss of weight or fever, as judged by the Investigator
- Severe psychiatric disease as judged by the Investigator
- Lack of suitability for participation in the study for any reason as judged by the Investigator
- Use of other probiotic products (according Sponsor's list) from Visit 1 and throughout the study
- Consumption of antibiotic drugs 1 month prior to screening and throughout the study
- Consumption of drugs on a regular basis which could interfere with symptom evaluation as judged by the Investigator

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-05-2014
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	20-03-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-10-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL46427.060.13