A randomised, placebo controlled double blind study to assess the efficacy of a probiotic dairy product containing Lactobacillus casei Shirota on symptoms, visceroperception and inflammation in Irritable Bowel Syndrome.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20968

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Irritable Bowel Syndrome (IBS) = Prikkelbare Darm Syndroom (PDS).
probiotics = probiotica
cytokine profiles = cytokine profielen
visceroperception = visceroperceptie
lowgrade inflammation = laaggradige ontsteking

Sponsors and support

Primary sponsor: Yakult Honsha Co. Ltd.
1-19, 1 Chome, Higashi-Shinbashi
Minato-ku 105-8660

Tokyo JAPAN
Contact person: Mr Oosawa
Contact person in Europe: Dr S Kudo or Dr J Zhao, science manager
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1332 EN ALMERE
The Netherlands
0031(0)365211300
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

To assess the effect of the probiotic product "Yakult" on symptoms in patients with IBS.

Secondary outcome

Secondary objective:

* To assess the effect of the probiotic product "Yakult" on quality of life in patients with IBS.

Exploratory objectives:

* To investigate the influence of the probiotic product on the intestinal flora composition of the IBS patients.

* To characterize the intestinal flora of the IBS patients by comparison to that of the healthy volunteers.

* To assess the effect of a 8 week treatment with the probiotic product on cytokine profiles in IBS patients.

* To assess the difference in visceroperception before and after treatment in the intervention group vs placebo group

* To assess the presence of low grade inflammation in sigmoid biopsies in IBS patients before and after treatment with probiotic or placebo

Study description

Background summary

N/A

Study objective

Treatment with a probiotic dairy product releives symptoms in Irritable Bowel Syndrome patients. It also improves quality of life of the patients, and has an positive effect on the composition of the microbiota. Cytokine stimulation profiles will differ before and after treatment with the probiotic product, and genetic cytokine profiles are different in (subtypes) of IBS patients compared to healthy controls.
Hypersensitivity of the rectum will be less after intervention with the probiotic product. Lowgrade inflammation will be less after intervention with the probiotic product, all the above compared to placebo treatment.

Study design

01-03-07 start inclusion period

01-06-08 end inclusion period

01-10-08 end follow-up period

01-05-09 end analysis period

Intervention

* Run in visit (week -6): inclusion following inclusion criteria, informed consent

* Start intervention visit (week 0): fecal analysis, start probiotics/placebo, collection of blood sample, barostat measurement, sigmoscopy for collecting 4 biopsies

* Intervention period visit (week 4): check of protocol with patient

* Intervention period visit (week 8): fecal analysis, collection of blood sample, barostat measurement, sigmoscopy for collecting 4 biopsies, after that stop probiotics/placebo

* Phone consultation (week 12): check of protocol with patient

* Follow-up visit (week 16): fecal analysis, end of study period

Contacts

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Eligibility criteria

Inclusion criteria

Patients will be included when:

1. Diagnosed with IBS according to the ROME II criteria.

2. Age between 18 and 65 years.

3. Giving informed consent

4. Minimum mean symptom score > 2 (scale 0-20 for the 5 symptoms: discomfort, pain, constipation, diarrhea and bloating) during pre run-in.

Exclusion criteria

1. Patients who have had gastrointestinal surgery resulting in gastric resection, small intestinal or colonic resection.

2. Patients who are allergic to milk protein

3. Patients who have a high intake of yogurt (over 500 ml per day)

4. Patients where LcS was detected before the start of sample ingestion in the fecal samples.

5. Patients not able to stop medication that influences stool frequency (laxatives or antidiarrhoeals)

6. Patients who are vegetarians.

7. Patients who have used probiotics in a period of four weeks prior to the start of the study.

8. Patients who have received antibiotics/antibacterials in a period of four weeks before the start of the study and during the intervention.

9. Patients who did not commit to drinking the minimum dosage of the samples

10. Patients whose submission of fecal samples was done after stopping drinking samples and

11. Patients who submitted fecal samples more than two days earlier than the end of the drinking period

12. Patients with any relevant neurological, cardiovascular, pulmonary, metabolic, haematological or endocrinic disorder that is not stabilised.

13. Patients who have participated in a clinical study with an unregistered (clinical trial) product within four weeks before the start of the study.

14. Patients with a history of drug or alcohol abuse.

15. Any medical condition which the investigator considers sufficiently serious to interfere with the conduct of the trial or that constitutes any risk to the patients.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2007
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	20-03-2008
Application type:	First submission

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
NTR-new	NL1190
NTR-old	NTR1235
Other	MEC : P05.131
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

N/A