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.

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20968

Bron
NTR

Verkorte titel
N/A

Aandoening

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

Ondersteuning

Primaire 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
Science department of Yakult Europe B.V.
Yakult Europe B.V.
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1332 EN ALMERE
The Netherlands
0031(0)365211300
Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

* 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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2007
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	20-03-2008

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1190
NTR-old	NTR1235
Ander register	MEC : P05.131
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A