GOS to Reduce Symptom Severity in IBS

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Let μT denote the mean value of the composite IBS-SSS score under treatment with the active / GOS and μP denote the mean value of the composite IBS-SSS score under placebo, then the primary two-sided hypothesis to be tested is: • H0: μT - μP = 0 (i....

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26014

Bron
Nationaal Trial Register

Verkorte titel
EGIS

Aandoening

Irritable Bowel Syndrome

Ondersteuning

Primaire sponsor: Clasado Research Services Ltd
Overige ondersteuning: Sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The difference in total IBS symptom severity between treatment arms as measured by mean composite IBS Symptom Severity Scale scores at the end of the study (Day 56).

Toelichting onderzoek

Achtergrond van het onderzoek

This is a Phase III, randomized, double-blind, placebo-controlled, multi-centre, 8-week intervention study, preceded by a 2-week run-in period, to assess the efficacy of (specific) galacto-oligosaccharides (GOS) on symptom severity in adult patients with IBS. The study population will consist of 210 adult patients diagnosed in the past 36 months with IBS-Diarrhoea (N =70), IBS-Constipation (N = 70), or IBS-Mixed (N =70). The study will be conducted in 5 sites in The Netherlands, Belgium and the UK.

Irritable bowel syndrome (IBS) is a highly prevalent and multifaceted functional bowel disorder characterized by recurrent abdominal pain associated with defecation or a change in bowel habits in the absence of detectable structural and biochemical abnormalities (Rome IV Criteria). Disordered bowel habits are typically present, such as constipation, diarrhoea or a mix of constipation and diarrhoea, as are symptoms of abdominal bloating/distension. The chronic and bothersome nature of IBS symptoms negatively affects patient quality of life and introduces a substantial economic burden on patients and the healthcare system. The gut microbiota composition and function may play a pivotal role in the pathogenesis of IBS, as a reduction in endogenous bifidobacteria, lactobacilli, and Faecalibacterium prausnitzii concentrations, as well as small bowel bacterial overgrowth have been reported in IBS patients, thereby introducing the gut microbiota as a potential target for treatment and symptom relief. Intervention with non-digestible food ingredients, such as GOS, may form a suitable intervention strategy, as these ‘prebiotics’ are known to modulate the gastrointestinal (GI) microbiota and support health and wellbeing of the host. The safety and efficacy of GOS has previously been evaluated in patients with IBS, which demonstrated that GOS may reduce IBS symptom severity, improve quality of life, improve stool consistency and defecation frequency and alter gut microbiota composition, in a safe manner. As there are currently limited suitable medical treatments for IBS, this study will evaluate the efficacy of a dietary supplement with GOS, in reducing symptom severity of patients with IBS.

Doel van het onderzoek

Let μT denote the mean value of the composite IBS-SSS score under treatment with the active / GOS and μP denote the mean value of the composite IBS-SSS score under placebo, then the primary two-sided hypothesis to be tested is:
• H0: μT - μP = 0 (i.e. no statistically significant change in IBS symptom severity after treatment)
• H1: μT - μP ≠ 0 (i.e. a statistically significant change in IBS symptom severity after treatment)

Success of the outcome is defined as statistically significant lower IBS-SSS scores at the end of the study (Day 56) in the active test group compared with placebo in the Intention-to-Treat population.

Onderzoeksopzet

Day -14 (Screening and ICF)
Run-in (2 weeks)
Day 0 (Randomization)
Week 1
Week 2
Week 4
Week 8 (End of study)

Onderzoeksproduct en/of interventie

GOS & Placebo

Contactpersonen

Publiek

Clasado Research Services Ltd.
Lucien Harthoorn

+31631905741

Wetenschappelijk

Clasado Research Services Ltd.
Lucien Harthoorn

+31631905741

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Diagnosed with IBS within 36 months prior to study entry
2. Confirmed IBS according to Rome-IV criteria (determined by Investigator)
3. An IBS Symptom Severity Scale score of ≥125 points at baseline
4. Male or female between 18 and 64 years of age (age ranges included)
5. Possession of a smartphone

6. Willing and eligible to provide consent and comply with protocol and product intake.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Unclassifiable IBS (IBS-U) as determined by Investigator
2. Use of products marketed as prebiotics, probiotics or synbiotics within 4 weeks prior to study entry.
o Regular cheese or yogurt containing lactic acid bacteria are not an exclusion criterion.
3. Systemic antibiotic or antimycotic treatment within 4 weeks prior to study entry
4. Use of laxatives or antidiarrheal medication within 4 weeks prior to study entry
5. Use of high-dose antidepressants/antipsychotics (>50mg) within 6 months prior to study entry. Low-dose antidepressants/antipsychotics should be stable for 3 months prior to study entry.
6. Confirmed lactose intolerance, defined as patients who report response to dietary elimination of lactose/dairy products. Confirmation is patient-reported and not done within the scope of this study.
7. Confirmed food allergy, with reported confirmation based on OFC, IgE, or skin prick test. Confirmation is patient-reported and not done within the scope of this study.
8. Galactosemia (galactose metabolism disorder)
9. Following diets likely to affect study outcomes, including:
o low FODMAP, KETO/high-fat, gluten free/coeliac, paleo, weight loss, caloric restriction, low-carb, 5:2/whole day energy restriction, Atkins/high-protein, sugar-free, single-food, juicing/any day of juicing, any other restriction diet (e.g. very low calory), or vegan diets (GOS is derived from cow’s milk).
10. Severe illness(es) or medical condition(s), including gastrointestinal pathologies:
o ulcers, coeliac disease, inflammatory bowel disease, bowel cancer, bowel resection, auto-immune diseases (e.g. Rheumatoid Arthritis, Systemic lupus erythematosus, Multiple Sclerosis, Graves’ Disease), bariatric surgery, acute or chronic diarrhoea secondary to confirmed infectious gastroenteritis, or enteral or parenteral nutrition
11. Surgical operations to the mouth or gastrointestinal tract within 4 weeks prior to study entry, or planned during the study
o Appendectomy within 6 months prior to study entry
12. Recent unintended weight loss:
o >5% of total body weight within 6 months prior to study entry
13. Excessive alcohol consumption (>10 units per week) and/or drug abuse
14. Pregnancy and lactation, or plan to become pregnant during the study period
15. Participation in other studies involving investigational or marketed products concomitantly or within 3 months prior to study entry
16. Changes in diet, supplement use or medication likely to affect study outcomes within 3 months prior to study entry or planned during the study (at the discretion of the Investigator).

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-07-2021
Aantal proefpersonen:	210
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL9317
Ander register	BEBO : Pending

Resultaten

Samenvatting resultaten
Planned