Darmboost

Gepubliceerd: 09-11-2020 Laatst bijgewerkt: 18-08-2022

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

Samenvatting

ID

NL-OMON23140

Bron
Nationaal Trial Register

Verkorte titel
Darmboost

Aandoening

gut complaints without medical diagnoses

Ondersteuning

Primaire sponsor: FrieslandCampina
Overige ondersteuning: FrieslandCampina

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary parameter is the gut comfort component score at day 21 of the study (component score is based on 5 questions: bloating, flatulence, stomach ache, constipation and diarrhea in the past 7 days)

Toelichting onderzoek

Achtergrond van het onderzoek

Prebiotics are important in steering the intestinal microbiota composition, and by doing so they can play an important role in the relief of ‘general’ gut complaints (not linked to a specific disease). Galacto-oligosaccharides (GOS) is a lactose derived prebiotic and fermented in particular by, and thus stimulating, bifidobacteria and lactobacilli. Besides a possible effect on gut complaints, emerging evidence finds a link between microbiota and brain function, known as the microbiome-gut-brain axis, affecting the regulation of the stress hormone cortisol and sleep quality. GABA produced by bifidobacterial and lactobacilli could play an important role in this process. Limited studies on the effect of GOS on general gut complaints have been performed in humans, whereas the combination of gut complaints, stress and sleep probably is unique. The primary objective is to assess the effect of 21 days of consumption of 5.5 g GOS powder on the gut comfort component score (based on 5 questions), as compared to a control group receiving maltodextrin (control product). Component scores are the average impression of the previous 7 days regarding bloating, flatulence, stomach ache, constipation and diarrhea at baseline and after 21 days. For this double-blind placebo controlled intervention study, 80 apparently healthy female human volunteers of 25-45 years with gut complaints (based on the component score of gut comfort ≥6) without a medical diagnosed disease as underlying cause will be included.

Doel van het onderzoek

We hypothesize that after 21 days of consuming GOS the component score of gut comfort in female adults of 25 – 45 years of age with self-reported gut related complaints is significantly lower (mean difference of at least 2 or more on the component score of gut comfort) compared to the control group.

Onderzoeksopzet

Baseline, day 4, day 14, day 21

Onderzoeksproduct en/of interventie

The intervention group receives 5.5g GOS. The control group receives the same amount of maltodextrin powder. Both groups need to use these powder supplements, portion packed in sachets, daily for 21 days. The powders can be added to a dairy product (e.g. yogurt, quark) or to a glass of water, juice, tea or coffee, and have to be consumed with the first meal of the day.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Female
- 25-45 years of age
- Component (summed) score for gut complaints ≥ 6 (based on bloating, flatulence, stomach ache, constipation, diarrhea)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Any medical diagnosed disease underlying gut-related complaints, including Irritable Bowel Syndrome, celiac disease, Crohn’s disease, colitis, haemorrhoids, cancer, and/or any other disease considered relevant as determined during screening.
- Use of antibiotics, opiates, anti-inflammatory drugs (NSAIDs) and/or metformin, and/or other medication that are known to affect the composition of the gut microbiota during the 14 days before inclusion.
- Pregnant or lactating.
- Self-reported lactose intolerance
- Self-reported cow’s milk protein allergy

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-12-2020
Aantal proefpersonen:	80
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	09-11-2020
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	NL9042
Ander register	METC Utrecht : METC-protocolnummer 20-530/D

Resultaten