Darmboost

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23140

Source
Nationaal Trial Register

Brief title
Darmboost

Health condition

gut complaints without medical diagnoses

Sponsors and support

Primary sponsor: FrieslandCampina
Source(s) of monetary or material Support: FrieslandCampina

Intervention

Outcome measures

Primary outcome

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)

Secondary outcome

- Component (summed) score of gut comfort after 4 and 14 days.

- Shifts in microbial composition (through 16s sequencing) after 21 days

Study description

Background summary

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.

Study objective

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.

Study design

Baseline, day 4, day 14, day 21

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

- 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

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2020
Enrollment:	80
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	09-11-2020
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	NL9042
Other	METC Utrecht : METC-protocolnummer 20-530/D

Study results