Evaluation of changes in gut transit time and gastrointestinal symptoms following the consumption of a fiber containing product in adults with constipation.

Published: 17-09-2014
Last updated: 21-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Interventional

Summary

ID

NL-OMON40696

Source
ToetsingOnline

Brief title
Fibers and Gut Health

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
Constipation, Stoppage

Research involving
Human

Sponsors and support

Primary sponsor: Nestec

Source(s) of monetary or material Support: Nestec

Intervention

Keyword: Fibers, Gastrointestinal, Gut, Obstipation

Outcome measures

Primary outcome

To evaluate change in whole gut transit time at the mid-consumption period timepoint (+2 weeks) in constipated patients consuming the study food product containing fiber in high quantity (Group 1), compared to those consuming placebo (Group 3).

Secondary outcome

• Assess change in gastrointestinal symptoms during the consumption period of the study food product

• Assess tolerance to the study food product

• Evaluate physiological and symptomatic endpoint(s) that best correlate with gut transit time

• Evaluate changes in regional (right colon, left colon, and rectosigmoid) colonic transit times at the mid-consumption period timepoint (+2 weeks)

• Evaluate change in whole gut transit time at the mid-consumption period timepoint (+2 weeks) in constipated patients consuming the study food product containing fiber in low quantity (Group 2), compared to those consuming placebo (Group 3)

Study description

Background summary

Gastrointestinal (GI) discomfort regularly affects >25% of the population worldwide. One of the major contributors to GI discomfort is constipation, which has a prevalence of ~15% (McCrea et al, 2008), and symptoms of which have a significant negative impact on the sufferer*s quality of life. The management of constipation remains challenging, with a high economic impact on the Dutch Health Insurance system. In 2013 within the Netherlands a total of ¤ 48 million was spent on medication for the treatment of obstipation, this was for just over 1 million patients using these type of drugs. Only a minority of patients consult a physician for these complaints, , thus there is a huge unmet need for food-based alternatives to the currently available prescription and over the counter laxatives and supplements in symptom management.

Dietary fiber supplements are widely used as a first-line treatment for constipation although little evidence exists to support its use in adults. The effectiveness of different fiber supplements is difficult to compare given wide differences in water-retention capabilities and effects on the colonic microbial ecology. Polydextrose is a type of soluble fiber that is partially fermented by the gut microbiota with a resulting increase in stool bulk and frequency as well as improved stool consistency and easier defecation.Because of these attributes, polydextrose is hypothesized to have benefit in people with constipation.

Study objective

The objective of this clinical trial is to evaluate the tolerance and effectiveness of 4 week supplementation of a proprietary polydextrose fiber product, in a dose-ranging fashion, on whole gut transit time and gastrointestinal symptoms in adults with functional constipation.

Study design

This will be a randomised, double-blind, , parallel study of three groups: Group 1: food product containing polydextrose in high quantity; Group 2: food product containing plydextrose in low quantity; Group 3: placebo.
• Study group 1: low high quantity fiber containing product
• Study group 2: high low quantity fiber containing product
• Study group 3: placebo

Intervention

The patients need to take twice a day one sachet during four weeks. The powder in the sachet needs to be mixed with 200ml of water.
• Study group 1: low high quantity fiber containing product (6g/sachet)
• Study group 2: high low quantity fiber containing product (4g/sachet)

• Study group 3: placebo

Study burden and risks

The patients need to visit four times within a period of four weeks. During two visit a fluoroscopic investigation will take place. For this patients need to take one radio-opaque capsule per day during six days before the investigation. During the four weeks the patients need to maintain a diary and complete several questionnaires.

Contacts

Public
Nestec

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Adult men or women (female subjects of child-bearing potential must be willing to use a reliable method of contraception throughout the study period)
• Age 18 - 75
• BMI: 18.5 - 29.9 kg/m2
• Symptoms of constipation for a minimum of 3 months
• Recruitment based on simplified core ROME III diagnostic criteria for functional constipation (based on specific screening questions):
o average Bristol stool type of 1 - 3 AND frequency of 1 - 3 spontaneous bowel movements (SBMs) per week
o plus at least ONE of the following at screening:
* straining on at least 25% of defaecations
* sensation of incomplete evacuation on at least 25% of defaecations
* sensation of anorectal obstruction / blockage on at least 25% of defaecations
* use of manual manoeuvres on at least 25% of defaecations.
• Cleveland Clinic constipation score (CCCS) of 8-20
• Low-moderate fibre intake (<=18g) determined by the semi-quantitative food intake screener known as the Block Fibre Screener
• Ability to understand the patient information sheet and instructions in Dutch, and able to provide informed consent

Exclusion criteria

• Subjects who report lactose intolerance and/or are allergic to soy or cow milk protein
• Pregnant or breast-feeding women
• Ongoing other diagnosed gastrointestinal disease or complication (Crohn's disease, Coeliac disease, chronic diarrhoea)
• Any clinical relevant abnormalities in the screening visit medical examination or alarm features such as sudden unintentional weight loss, rectal bleeding, recent change in bowel habit (<3 months), abdominal pain and stool positive for occult blood
• Prior abdominal surgery (including gastric bypass or laparoscopic banding), except cholecystectomy and appendicectomy
• Neurologic diseases such as multiple sclerosis, stroke, spinal cord injury, Hirschsprung disease
• Chronic medication that in opinion of the investigator would impact gut motility
• Illness that may preclude the subject's ability to complete the study or that may confound the study outcomes (e.g. bowel cancer, prostate cancer, terminal illness, severe cardiovascular disease, chronic renal failure or eating disorders) or any other serious illness resulting in >2 weeks inability to work in the 3 months before the study start
• Subjects with co-morbid illnesses such as cardiovascular, endocrine, renal or other chronic disease likely to affect gut motility or limit normal functions (e.g. reduced mobility or increased fragility)
• Ongoing alcohol, drug, or medication abuse (anamnesis only)
• Self-reported symptoms of pelvic organ prolapse
• Moderate or severe active local anorectal problems such as recurrent anal fissures, bleeding, large prolapsing haemorrhoids, etc

• Regular use of fibre supplementation (e.g. Fybogel, Lactulose) over the week prior to the screening visit and no more than 6 standard doses in the past 1 month prior to the screening visit
• Participation in another study with any investigational product within 3 months of screening
• Investigator believes that the participant is physically or mentally unfit to participate in the trial

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-12-2014
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	17-09-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-01-2015
Application type:	Amendment

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-03-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
CCMO	NL49753.100.14