Effects of inulin on bowel habit in elderly people with a low frequency of defecation

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A low frequency of defecation (constipation) is a common complaint affecting a large part of the population. Children, adults and elderly can experience chronic inconvenience because of this complaint. Inulin is not digested in the human...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON33185

Source
ToetsingOnline

Brief title
Inulin and bowel habit in elderly

Condition

- Other condition

Synonym
Mild constipation

Health condition

Trage stoelgang

Research involving
Human

Sponsors and support

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

Intervention

Keyword: elderly, inulin, mild constipation

Outcome measures

Primary outcome

The primary question is: does inulin consmption increase the defecation

frequency as compoared with the placebo. This frequency is assessed by a bowel

habit questionnaire filled in by the participants at certain times during each

treatment.

Secondary outcome

Secondary outcomes are the effect of inulin on gastrointestinal comfort

(flatulence etc.) and on quality of life.

Study description

Background summary

Inulin occurs as a carbohydrate in a variety of plants: onion, garlic, wheat, Jerusalem artichoke and chicory, that all belong to our daily nutrition. Sensus (part od Royal Cosun) manyfactures inulin from chicory roots. This product with the brand name Frutafit is sold world wide to the food industry for application in virtually all market segments, but especially in dairy and bakery, in infant food, in breakfast cereals and ceral bars, in beverages, but also in meat products and in suaces and dressing it finds applications.
In these applications inulin is used not only to increase the dietary fibre conntent, but also as a sugar and fat replacer, as a texturising agent and for its prebiotic properties. For these and other health effects to be used as health claims on foods a solid scienitific basis is required.

Study objective

A low frequency of defecation (constipation) is a common complaint affecting a large part of the population. Children, adults and elderly can experience chronic inconvenience because of this complaint. Inulin is not digested in the human gastrointestinal tract and it is therefore considered a soluble dietary fibre. These food ingredients are well known for their positive effects on bowel habit.
Ths research is set up to show that consumption of inulin can improve the bowel habit in slightly constipated elderly.

Study design

The study will be a cross-over, placebo controlled study. Each treatment will last 5 weeks with a wash-out period of 2 weeks in between. The participants receive a dosage of 2 times 5 gram inulin or maltodextrin (placebo) per day in a drink and as a powder in a sachet; hence the total inulin or placebo consumption will be 10 g/d.

Intervention

Once a day people consume an orange juice drink with 5 g of inulin or placebo maltodextrin, and once a dya they use a powder (mixed with for instance coffe or tea) of 5 g inulin or placebo during 5 weeks per treastment. Hence the total consumption will be 10 g/day or inulin or placebo. A wash-out period of 2 weeks in between treatments will be used.

Study burden and risks

The burden and risks are very limited: inulin and the placebo are components of our daily diet. Inulin is used already for about 20 years as an ingredient in food industry without complications. This research does not use any invasive measures and the volunteers can stick to their normal dietary habits and lifestyle. The burden involves only the discipline to consume for 2 x 5 weeks an inulin- or placebo containing drink, and to use a powder product. Filling in the bowel habit and QoL questonnaires does not take much time.
In very rare cases an allergic reaction to inuln-containing products has been reported, but the risk for such an event is extremely low.

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Low defecation frequency (max 3 times per week), age between 50 - 75 y

Exclusion criteria

Use of laxatives

Study design

Design

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

Control:	Placebo
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-05-2010
Enrollment:	54
Type:	Actual

Ethics review

Approved WMO

Date:	26-08-2009
Application type:	First submission
Review commission:	IRB Amsterdam: Independent Review Board Amsterdam (Amsterdam)

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	NL27269.003.09