

# 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...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	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 consumption increase the defecation frequency as compared 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 of Royal Cosun) manufactures 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 cereal bars, in beverages, but also in meat products and in sauces and dressing it finds applications. In these applications inulin is used not only to increase the dietary fibre content, 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 scientific 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.

This 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 day they use a powder (mixed with for instance coffee or tea) of 5 g inulin or placebo during 5 weeks per treatment. Hence the total consumption will be 10 g/day of 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 questionnaires does not take much time.

In very rare cases an allergic reaction to inulin-containing products has been reported, but the risk for such an event is extremely low.

## **Contacts**

### **Public**

Sensus

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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