

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

Submission date 12/02/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/06/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 13/02/2018	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The company Sensus BV produces the food ingredient inulin, a type of soluble vegetable fibre extracted from chicory roots. Unsatisfactory bowel function occurs in many healthy adults, in particular among older people. However, while medical treatments (laxatives) developed for treatment of clinical constipation are effective against unsatisfactory bowel function, these treatments also have serious drawbacks. In particular it can be difficult to re-establish normal bowel function after long term use of laxatives. There is therefore a need to develop food-based strategies for safe self-management of unsatisfactory bowel function. It is known that consumption of fibre-rich vegetables tends to enhance and stabilise bowel function, possibly by providing good substrates for beneficial types of gut bacteria, but there are only few studies specifically investigating inulin.

The aim of the study is to measure the effect of inulin consumption on the stool frequency and stool consistency in healthy adults with unsatisfactory bowel function.

What does the study involve?

The study consists of two study periods each of 5 weeks, with at least two weeks between the periods. Participants will receive either the active inulin product (in the form of a sachet which is mixed with juice or another cold drink) or a placebo product (a dummy product with similar taste and appearance, but no fibre content) to take twice a day for 5 weeks. After a break of at least 2 weeks, they will then have another 5 weeks of taking the other product (either the inulin or the placebo). This means that all participants will have the chance to try the active product during one of the two study periods they take part in.

Who can take part?

For this study we are looking for 22 men and women, between the age of 50 - 75 who are generally healthy, but have low stool frequency (2 days or more per week without successful bowel movements) and do not take any medication for it. Participants will be required to attend visits at Newcastle University.

When does the study take place?

The study period is from 8th December 2011 to 20th June 2012.

Where does the study take place?

The study takes place at Newcastle University, in Newcastle upon Tyne, United Kingdom.

What are the benefits and risks to participants?

The benefit to participants is that if the product works, their well-being will benefit during the treatment period. Since the study product is a widely used food ingredient and several common foods can provide doses corresponding to those used in the study, any participant who feels that their bowel function has improved during (part of) the trial will be able to choose to continue treatment after the completion of the study and achieve the corresponding benefits (whether or not the perceived benefits are caused by the product itself or are a placebo effect). The following potential risks were identified: 1. Possible minor side effects (flatulence, stomach rumbling) when consuming the study product; 2. Possible health risk if the study product gets wet and subsequently becomes mouldy; 3. Possible embarrassment when transporting stool samples, e.g. on public transport. Appropriate management procedures have been implemented to control each of these risks.

Who is funding the project?

The study will be financed by Sensus BV, Rosendaal, the Netherlands.

Who is the main contact?

Miss Carolyn Taylor, trials assistant.

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Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

BH102085

Study information

Scientific Title

Effects of Inulin versus placebo on bowel function in older people with a low Frequency of defecation

Acronym

InuFre

Study objectives

The principal question of this study is to quantify the effect of native inulin on the stool frequency and stool consistency in slightly constipated older people using validated questionnaires.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Newcastle University Sage Faculty Ethics Committee, reference number BH102085, 01/12/2011

Study design

Randomised double-blind placebo-controlled cross-over study

Primary study design

Interventional

Study type(s)

Screening

Health condition(s) or problem(s) studied

Bowel function (unsatisfactory stool frequency)

Interventions

Intervention: Inulin from chicory roots, 10g daily orally

Placebo: Maltodextrin, 10g daily orally

5 weeks treatment followed by 2 weeks washout then 5 weeks treatment.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Stool frequency measured by diary, kept daily during weeks 1, 3 and 5 of each intervention period

Key secondary outcome(s))

1. Self-reported stool consistency measured using the Bristol scale
2. Patient assessment of constipation (PAC-SYM) questionnaire

Completion date

20/06/2012

Eligibility

Key inclusion criteria

1. Healthy volunteers
2. Men and women aged between 50 and 75 years
3. Low stool frequency (2 days or more per week without successful bowel movements)

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Senior

Sex

All

Key exclusion criteria

1. Clinical constipation as defined by the Rome criteria
2. Anatomical cause of reduced bowel function
3. History of colonic or anal surgery
4. Current or recent (<5 years) diagnosis of cancer, coronary heart disease or diabetes
5. Inflammatory bowel diseases (Crohns disease, ulcerative colitis)
6. Use of antibiotics, laxatives or diuretics in the last 3 months
7. Current or recent (<3 months) use of opium preparations
8. Any other condition that in the view of the participants GP may make the participant unsuitable for the trial

Date of first enrolment

08/12/2011

Date of final enrolment

20/06/2012

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Human Nutrition Research Centre
Newcastle upon Tyne
United Kingdom
NE1 7RU

Sponsor information

Organisation

Newcastle University (UK)

ROR

<https://ror.org/01kj2bm70>

Funder(s)

Funder type

Industry

Funder Name

Sensus BV (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes