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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

Registration date
12/06/2012

Overall study status
Completed

Last Edited
13/02/2018

Condition category
Digestive System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 enhances and stabilises 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 to 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.
Telephone: 0191 222 3592 or 07583252204
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http://research.ncl.ac.uk/InuFre

Study website
http://research.ncl.ac.uk/FHN/page.php?index=4

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Screening

Participant information sheet
Patient information sheet can be found at http://research.ncl.ac.uk/FHN/cmsDocs/inulin%20Information%20sheet%20final.pdf

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

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

Overall study start date
08/12/2011

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

Age group
Senior

Sex
Both

Target number of participants
22

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
England

United Kingdom

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

Sponsor information

Organisation
Newcastle University (UK)

Sponsor details
Human Nutrition Research Centre
School of Agriculture, Food and Rural Development
Newcastle upon Tyne
England
United Kingdom
NE1 7RU

Sponsor type
University/education

ROR
https://ror.org/01kj2bm70

Funder(s)

Funder type
Industry

Funder Name
Sensus BV (Netherlands)

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration