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Rye bread fermentable carbohydrates and abdominal symptoms in irritable bowel syndrome – A postprandial study

Submission date
18/02/2016

Recruitment status
No longer recruiting

Registration date
25/02/2016

Overall study status
Completed

Last Edited
28/03/2019

Condition category
Digestive System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Irritable bowel syndrome (IBS) is a common, long-term condition that affects the digestive system. The symptoms can vary from person to person and often include abdominal (tummy) pain, bloating and changes in bowel habits (from constipation to diarrhoea). The exact cause of IBS is not known, however many think that it is related to overactivity in the gut causing problems digesting food properly. There is no cure for IBS but treatments such as lifestyle and dietary changes can help to ease the symptoms. Fermentable, Oligo-, Di- and Mono-saccharides and Polyols (FODMAPs) are short chains of sugar which are very easy for the body to break down. In the large intestine, bacteria that naturally helps with digestion quickly ferments (turns into alcohol) these sugars which can make the symptoms of IBS worse. Traditional rye bread is an important part of a healthy diet in Finland but the FODMAPs it contains may make symptoms worse in people with IBS. Rye bread that contains less fermentable carbohydrates (low-FODMAP) could be a good alternative for those who get abdominal symptoms from the traditional rye bread. The aim of this study is to compare the effects of eating traditional rye bread and low-FODMAP rye bread in IBS sufferers.

Who can participate?
Normal weight and overweight women aged between 18 and 65 who have IBS

What does the study involve?
The study involves two separate test periods which are spaced 2-4 weeks apart. One involves eating low-FODMAP rye bread and the other involves eating traditional rye bread. The participants take part in both test periods but they are taken in a random order. At the beginning of each test period participants swallow a small wireless motility capsule (a device which monitors pH (how acid or alkaline the gut is), pressure and temperature) and eat the 8 slices of bread. Over the following 12 hours, participants are asked about any IBS symptoms they are having and breathe into a machine to record the amount of hydrogen their gut is producing (a sign of fermentation) every half an hour. After this, these tests are repeated every 3 hours until the wireless motility capsule (WMC) leaves the body in a bowel movement. The time taken for the WMC to leave the body is also recorded.

What are the possible benefits and risks of participating?
There are no direct benefits of taking part, although participants are able to receive information about the state of their health. Risks of participating include a small chance that the WMC is not passed and remains in the body, although measures will be taken to resolve the issue should it occur.

Where is the study run from?
University of Helsinki (Finland)

When is the study starting and how long is it expected to run for?
January 2016 to June 2016

Who is funding the study?
Fazer Bakeries Ltd. (Finland)

Who is the main contact?
Dr Riitta Freese

Contact information

Type(s)
Scientific

Contact name
Dr Riitta Freese

Contact details
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Additional identifiers

Protocol serial number
01/2016

Study information

Scientific Title
A postprandial study on the effect of fermentable carbohydrates (FODMAP) in rye bread on abdominal symptoms in patients with irritable bowel syndrome

Study objectives
The aim of the study is to compare participants' postprandial abdominal symptoms when they eat low-FODMAP rye bread vs. traditional rye bread.

Hypotheses:
1. After eating the low-FODMAP rye bread participants will have less abdominal symptoms to and the production of hydrogen in the colon is lower compared to the symptoms and hydrogen levels after eating the traditional rye bread
2. The pressure will be lower and the pH higher with low-FODMAP rye bread vs. traditional rye bread

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hospital District of Helsinki and Uusimaa Ethics Committee of Medicine, 16/12/2015, ref: 411/13 /03/01/2015

Study design
Randomized double-blind crossover trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Irritable bowel syndrome

Interventions
The study consists of two test periods and every participant participates both treatments in a randomised order:

1. A postprandial test with the low-FODMAP rye bread (8 slices)
2. A postprandial test with the traditional rye bread (8 slices)

In each test period, the participant swallows the wireless motility capsule (WMC) and eats 4 slices of bread. After 6 hours and after 10-12 hours the participant eats 2 slices of bread on each meal, that makes total 8 slices during three meals. During the follow-up period, that starts after the WMC is swallowed, gastrointestinal symptoms questionnaires and hydrogen breath test are conducted every half an hour for 12 hours and every three hours during the following days until the WMC is defecated. The treatment is given in the first day of the test period, and the test period will take five days maximum. The test period ends, when the WMC is defecated. There is a 2-4 weeks wash out period between the test periods.
The order of the treatments (low-FODMAP rye bread vs. traditional rye bread) is determined by simple randomisation (random number table).

Intervention Type
Other

Primary outcome(s)
1. Gastrointestinal symptoms are measured using a visual analogue scale (VAS) questionnaire every half an hour for 12 hours and then every three hours until the wireless motility capsule

(WMC) is defecated
2. Hydrogen production is measured using a hydrogen breath test device (Gastrolyzer®, Bedfont Scientific, UK) every half an hour for 12 hours and then every three hours until the WMC is defecated
3. Gastrointestinal pH is measured using the wireless motility capsule (SmartPill®, Given Imaging, GA, USA) during the whole test period
4. Gastrointestinal pressure is measured continuously using the wireless motility capsule (SmartPill®) during the whole test period

Key secondary outcome(s))
1. Gastrointestinal temperature is measured continuously using the wireless motility capsule (SmartPill®) during the whole test period (until the WMC is defecated)
2. Transit time is measured continuously using the wireless motility capsule (SmartPill®) during the whole test period (until the WMC is defecated)

Completion date
30/06/2016

Eligibility

Key inclusion criteria
1. Female
2. Aged between 18 and 65 years
3. Irritable bowel syndrome (Rome III criteria)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Pregnancy or breastfeeding
2. Regular smoking
3. Implanted electrical device (e.g. artificial cardiac pacemaker)
4. Significant abdominal surgery (e.g. bowel resection)
5. Celiac disease
6. Crohn’s disease
7. Diverticulitis
8. Dyspepsia
9. Dysphagia

10. Stomach bezoar
11. Suspicion of intestinal stenosis
12. Difficult constipation or medication that affects intestinal motility
13. Hormonal, renal, blood or liver disease
14. Participation in other clinical trial in less 2 months before the study

Date of first enrolment
01/03/2016

Date of final enrolment
30/03/2016

Locations

Countries of recruitment
Finland

Study participating centre
University of Helsinki
Department of Food and Environmental Sciences (Nutrition)
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Sponsor information

Organisation
Fazer Bakeries Ltd.

ROR
https://ror.org/02d4f0r15

Funder(s)

Funder type
Industry

Funder Name
Fazer Bakeries Ltd.

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available as due to the nature of the measurements (repeatedly measured physiological parameters) the participant level dataset is extensive. The dataset will be kept at the University of Helsinki and the contact person is Dr Riitta Freese.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	21/03/2018		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes