Gastric and neural correlates of bloating

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Determine the gastric and neural correlates of bloating.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal signs and symptoms
Study type	Interventional

Summary

ID

NL-OMON42621

Source
ToetsingOnline

Brief title
Gastric bloating MRI (BLOB)

Condition

- Gastrointestinal signs and symptoms

Synonym
Bloating, dyspepsia

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W,Heineken BV

Intervention

Keyword: functional MRI, Gastric discomfort, Gender differences, Magnetic resonance imaging

Outcome measures

Primary outcome

1) Gastric measures (MRI): Gastric volume, air and liquid gastric compartments. 2) Subjective ratings of fullness and bloating. 3) Changes in regional brain activity in brain regions associated with visceral perception and processing, as assessed with perfusion fMRI.

Secondary outcome

Subjective feelings of appetite, thirst and nausea.

Study description

Background summary

Carbon dioxide contained in beverages can increase gastric volume, consequently inducing a feeling of epigastric discomfort. Women are more subject to dyspepsia, and gastric discomfort. In line with this bloating and fullness sensations are often described by women as a limiting factor to beer consumption, but surprisingly not to soft drink consumption. However, the gastric and neural correlates of gastric bloating are ill-explored.

Study objective

Determine the gastric and neural correlates of bloating.

Study design

Randomized cross-over study with two treatments.

Intervention

Drinking 500 mL beer (1x training, 1x test) and a carbonated softdrink (1x) in 20 min.

Study burden and risks

The study will consist of an information meeting (~30 min), a training session

(~60 min; up to 30 min questionnaires, 20 min drinking test, 10-min dummy MRI session) and two MRI sessions (~90 min each). During the MRI sessions participants will repeatedly rate their gastric feelings, drink 500 mL of either beer or a lemonade in 20 min and be scanned at baseline (t0) and 4 times at 10 min intervals after drinking (t25, t35, t45, t55; total time in scanner: 50 min). The study is non-therapeutic to the participants. The risk associated with participation is negligible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

-Age: 18-40 years
-BMI: 18.5 - 25.0 kg/m2
-Healthy (as judged by the participant)

-On average consuming more than 1 unit of beer per month but less than 13 units per week.
-On average consuming more than 1 unit of soft drink per month but less than 13 units per week.
-Willing to be informed about incidental findings of pathology and approving of reporting this to their general physician.

Exclusion criteria

-Drug use or medical conditions which may interfere with normal functioning of the digestive tract. -Drug use or medical conditions which may interfere with normal functioning of the circulatory system
-Drug use or medical conditions which may lead to unreliable fMRI results (including, but not limited to neurological conditions)
-Reported unexplained weight loss or weight gain of > 5 kg in the month prior to pre-study screening
-For women: having the intention to become pregnant, pregnancy during the last 6 months or lactating
- Smoking on average more than one cigarette/cigar a day
-Having a contra-indication to MRI scanning including, but not limited to, metal in the body and claustrofobia

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-10-2015
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	28-08-2015
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

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	NL54050.081.15