Gastric and neural correlates of bloating

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23012

Source
Nationaal Trial Register

Brief title
BLOB

Health condition

Bloating, dyspepsia
Opgeblazen gevoel, dyspepsia, maagklachten

Sponsors and support

Primary sponsor: Wageningen UR (University & Research centre)
Source(s) of monetary or material Support: Wageningen UR, Heineken BV.

Intervention

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

Secondary outcome

Subjective feelings of appetite, thirst and nausea; obtained on scan days just before and after participants are scanned.

Study description

Study objective

Beer induces more bloating than carbonated soft drinks and this effect is more prominent in women compared to men as measured from theh stomach and in regional brain activation.

Study design

Two study days.

Intervention

Consumption of 500 mL beer or carbonated soft drink.

Contacts

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Eligibility criteria

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
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-10-2015
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	01-10-2015
Application type:	First submission

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
NTR-new	NL5309
NTR-old	NTR5418
Other	NL54050.081.15 : CCMO

Study results