Measuring gastric emptying by use of MRI

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The objective of this study is to validate MRI as a functional measuring device for directly monitoring gastric emptying in vivo, while creating an overview of the influence of viscosity and nutrient density on gastric emptying times.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON41043

Source
ToetsingOnline

Brief title
StoMagnet

Condition

- Other condition

Synonym
fysiologie of gastric emptying

Health condition

normale fysiologie van het Maagdarmstelsel

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: EU framework 7

Intervention

Keyword: Food passage, Gastric Emptying Rate, MRI, Satiety

Outcome measures

Primary outcome

The main study parameter is stomach size/content as measured by MRI over a time of 2 hours. The outcome of the study is the difference in these measured parameters between the 4 treatments.

Secondary outcome

Participants will be asked to rate their feelings of appetite on a questionnaire just before and after they are scanned. This questionnaire will consist of four dimensions of appetite, i.e. hunger, fullness, desire to eat and prospective consumption. Moreover, participants will rate their thirst, and wellbeing i n this questionnaire. In addition, palatability and desire to consume the stimuli will be rated in the scanner. Responses will be reported on 100-mm visual analogue scales.

Exhaled air is measured for for isotopic enrichment using mass spectrometry, in order to compare this with the MRI data.

Study description

Background summary

After ingesting food, the bolus ends up in the stomach. The stomach has many functions, from secreting digestive fluids to kneading the contents and early absorption of small amounts of specific nutrients. The time food resides in the stomach is not only relevant for these processes, but also for the feeling of *being full*. Though there are indirect ways to measure the gastric emptying rate, better and more direct measuring techniques can yield better understanding and more accurate scientific research. Magnetic Resonance Imaging (MRI) offers the possibility to directly observe the process of gastric emptying.

Study objective

The objective of this study is to validate MRI as a functional measuring device for directly monitoring gastric emptying in vivo, while creating an overview of the influence of viscosity and nutrient density on gastric emptying times.

Study design

The study has a randomized crossover design (within subject design) in which participants ingest 500 ml liquid meals (or a 500 ml water control), which differ in viscosity and nutrient content. The shakes are marked with a 13C stable isotope, in order to measure gastric emptying using mass spectrometry on exhaled air, this is the current clinical measure of gastric emptying.

Stimuli:
Shake B
Low viscosity - High nutrient
Shake D
High viscosity - High nutrient
Shake A
Low viscosity - Low nutrient
Shake C
High viscosity - Low nutrient

Control
Water

Overview of study for one participant:
Screening, scan session 1, scan session 2, scan session 3, scan session 4,

Scan session:
Arrival, sign MRI form, lie down in scanner: scan of empty stomach, drink random shake, scan very 10 minutes of stomach for 2 hours including exhaling in a sample bag, end session

Each participant will randomly be assigned an order of shakes. Also at a random

session out of the 4 the liquid shake will be preceded by the water control.
The sessions will be planned with at least one day apart.

Intervention

Stimuli:
Shake B
Low viscosity - High nutrient
Shake D
High viscosity - High nutrient
Shake A
Low viscosity - Low nutrient
Shake C
High viscosity - Low nutrient

Control
Water

Study burden and risks

The study has no direct benefits to the participants, with the possible exception of getting a drinkable meal.
The study is non-therapeutic, The risk associated with the study is deemed 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

Male
18-35
BMI: 18.5 - 25.0 kg/m2
Healthy as judged by the participant

Exclusion criteria

• Failing to meet one or more of the inclusion criteria
• Having difficulties with swallowing/eating
• Weight loss or weight gain of 5 kg or more during the last two months
• Having an endocrine or gastrointestinal disorder which may affect gastric emptying.
• Being allergic/intolerant for products under study (see form F1)
• Working at the Division of Human Nutrition (WUR)
• Current participation in other research from the Division of Human Nutrition (WUR)

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-06-2014
Enrollment:	17
Type:	Actual

Ethics review

Approved WMO

Date:	15-04-2014
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	NL48059.081.14