MaagNeet

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22951

Source
NTR

Health condition

gastric emptying
maag lediging

Sponsors and support

Primary sponsor: WUR
Source(s) of monetary or material Support: EU F7

Intervention

Outcome measures

Primary outcome

The main study parameter is stomach content as measured by MRI over a time of 2 hours.

Secondary outcome

The secondary outcome of the study is the difference in these measured parameters between the 4 treatments.

Study description

Background summary

Rationale: 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.

Objective: The primary objective of this study is to validate MRI as a functional measuring device for directly monitoring gastric emptying in vivo.

Study design: In this study participants will drink 4 different liquid meals and a water control. The gastric filling and emptying by these loads will be measured by use of MRI. The order in which participants are exposed to the four different liquid meals is randomized and counterbalanced.

Study population: The study population consists of 20 apparently healthy, normal weight (BMI 20-25 kg/m2) men between 18 and 35 years old.

Main study parameter/endpoint: The main study parameter is gastric content (mL).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The screening will consist of measurement of body height and weight and filling out several questionnaires (approx. 15 min) and an introductory Q&A session (approx. 15 min). If the participant’s initial questionnaire yields no objections and they are still interested after hearing the explanation of the study, they will be included in the study. For the study, participants will visit the MRI facility in Hospital Gelderse Vallei (Ede) four times (trial duration approx. 150 min). The subjects will scanned using MRI to measure their stomach volume before the treatment, and then be asked to drink one of the liquid meals. Questions will be asked about their hunger state and fullness. The study is non-therapeutic to the participants. The risk associated with participation is negligible (comparable with normal day to day

activities).

Study objective

The primary objective of this study is to validate MRI as a functional measuring device for directly monitoring gastric emptying in vivo

Study design

Intervals of 10 minutes

Intervention

Shakes differing in viscosity and nutrient content

Contacts

Public
Wageningen Universiteit
Guido Camps
Wageningen
The Netherlands
Scientific
Wageningen Universiteit
Guido Camps
Wageningen
The Netherlands

Eligibility criteria

Inclusion criteria

• Age: 18-35 years

• BMI: 18.5 – 25 kg/m2

• Healthy (as judged by the participant) (see form F1)

• Willing to comply with the study procedures

• Willing to be informed about incidental findings of pathology

• Having given written informed consent (see form E2)

• Having signed the MRI screening form (as mandated by the hospital, see form F2)

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:	Observational non invasive
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	15-05-2014
Enrollment:	17
Type:	Unknown

Ethics review

Positive opinion

Date:	02-05-2014
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	NL4450
NTR-old	NTR4573
Other	METC number : 14/06

Study results