

# Pilot study: Gastric emptying with 13C breath test

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Appetite and general nutritional disorders
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON31414

### Source

ToetsingOnline

### Brief title

Gastric emptying

### Condition

- Appetite and general nutritional disorders

### Synonym

anorexia verlies van eetlust

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Wageningen Universiteit

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** anorexia of ageing, breath test, energy content, gastric emptying

## Outcome measures

### Primary outcome

The main study outcome is gastric emptying (and the variation in that measurement). Gastric emptying will be measured with a non-invasive breath test. The subject will come in fasting state to the research centre and ingest the test product which is labelled with  $^{13}\text{C}$ . The test foods consist of 2 experimental cooked foods, differing in energy content. Each food will be measured in duplicate. Breath samples will be collected before consumption of the food and at 15 minute intervals during 4-6 hours. Breath samples will be analyzed on concentration of  $^{13}\text{C}$ .  $^{13}\text{C}$  recovery ( $T_{1/2}$  and  $T_{lag}$ ) will be used as a measure for gastric emptying.

### Secondary outcome

Secondary, appetite and wellbeing ratings will be measured during the test (Visual Analogue Scales).

## Study description

### Background summary

Meal termination is mainly caused by the volume of food via stretch receptors in the stomach. It might be that in older people gastric distension is increased due to gastroparesis and/or delayed gastric emptying. This may lead to smaller meals and eventually in anorexia of ageing.

By means of this pilot we aim to set up a non-invasive method to measure gastric emptying, and more important, we are getting information on the within and between subject variation of this measurement. For future research purposes, we are especially interested in the effects of ageing and the effects

of certain foods or meals.

### **Study objective**

The primary objective is twofold; first to get information on the between subject variation in gastric emptying to make between group comparisons (young adults vs. elderly). Second, to obtain information on the within subject variation of gastric emptying to make within subject comparisons (low vs. high energy content).

### **Study design**

Observational study with 4 gastric emptying measurements per subject and 2 study groups.

### **Study burden and risks**

Subjects will have to come 4 times to the research centre to undergo the breath test (4-6 hours). Prior to participation subjects will have a screening visit of ca. 15 minutes (inclusion questionnaire; measurement of weight and height; explanation of the procedure).

The study is non-therapeutic to the participant. The risk associated with participation is negligible. Compared to other studies, the burden can be considered as low. No invasive measurements are present.

## **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

Apparently healthy, as judged by the subject

Age: Young adults: 18-30 year, Older adults: 60-80 year

Used to eating breakfast (> 5 times per week)

### Exclusion criteria

Weight change of >5kg during the last 2 months

Being on a weight loss diet

On a prescribed diet that interferes with the study foods

Bowel or stomach disorder

Diabetes or thyroid disorder

Food intolerance or allergy for foods that are provided during the study

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

## Recruitment

NL  
Recruitment status: Recruitment stopped  
Start date (anticipated): 01-10-2007  
Enrollment: 10  
Type: Actual

## Ethics review

Approved WMO  
Date: 11-11-2007  
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	NL19415.081.07