

# Adherence of PREprocedural eating and drinking before a oesophasal-gastro-duodenoSCOpY to shorten prolonged fasting: A pilot study

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Objective: to determine the feasibility of planned eating and drinking in preparation for oeshophagus-gastroduodenoscopy.

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

## Summary

### ID

NL-OMON49346

### Source

ToetsingOnline

### Brief title

PREpare for oesophasal-gastro-duodenoSCOpY (PRESCO)

### Condition

- Gastrointestinal signs and symptoms

### Synonym

fasting, gastric investigation, gastroscopy

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Ziekenhuisvoorzieningen Gelderse Vallei

**Source(s) of monetary or material Support:** Ziekenhuis Gelderse Vallei - Researchfonds

## Intervention

**Keyword:** Fasting, Food intake, Oesophasal-gastro-duodenoscopy, pilot study

## Outcome measures

### Primary outcome

Primary feasibility outcomes are reach and recruitment, dose received, fidelity and limited efficacy. Reach and recruitment will be measured with inclusion rate and barriers to participate. Dose will be measured as patients satisfaction and barriers for adherence. Fidelity will be measured with adequate fasting time. Limited efficacy will be estimated with gastric visibility and comfort.

### Secondary outcome

Secondary effectiveness outcomes are time of procedures, and complications.

## Study description

### Background summary

Background: Fasting before oesophago-gastro-duodenoscopy (OGD) is necessary for a clear view on the mucosa. Prolonged fasting periods leads to discomfort in patients with symptoms as thirst, hunger, anxiety, and stress. Preprocedural glucose loading leads to less preoperative discomfort.

### Study objective

Objective: to determine the feasibility of planned eating and drinking in preparation for oesophagus-gastroduodenoscopy.

### Study design

Design: a non-controlled pilot study.

### Intervention

Intervention: Patients will be instructed to eat until six and drink until two hours in preparation of the gastroscopy. patients can choose to consume standardized products. The standardized meal contained 357 kcal of energy, 15.7 gram protein, and 8.8 gram fats and is to be consumed at least 6,5 hours before the gastroscopy. The standardized drinks had a volume of 150ml and contained 58kcal of energy and was to be consumed at 2 hours before the gastroscopy.

### **Study burden and risks**

Ethics: Patients are requested to provide informed consent before participation. Data collection with questionnaires will take approximately 15 minutes. Eating and drinking will benefit their comfort in preparation of the scopy, however, strict adherence to the instructions may result in eating during the night.

## **Contacts**

### **Public**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

## Inclusion criteria

patients who are planned for gastroduodenoscopy at outpatient clinic basis;

- if they were 18 years old and beyond,
- if they were able to consume foods per mouth
- provided informed consent.

## Exclusion criteria

- patients who have had bariatric surgery
- patients with had a clinical proven gastropareses or absence of swallow reflex
- patients with diabetes mellitus

## Study design

### Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Health services research

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 24-06-2020

Enrollment: 48

Type: Actual

## Ethics review

Approved WMO

Date: 01-09-2020

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
CCMO	NL73331.081.20