

# Has a large glass of milk or yoghurt passed through the stomach 4 hours after intake?

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<b>Registration date</b> 15/01/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 05/02/2020	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Preoperative fasting is routinely applied before any procedure with general anaesthesia, with the goal of avoiding the risk of aspiration of gastric contents into the trachea (breathing tube). However, the safe limits for ingestion are not well defined. Studies in children suggest that a limited quantity of semisolid food, e.g. milk products, may be eliminated from the stomach well within a fasting period of 4 hours, which is shorter than the currently prescribed 6 hours. The primary aim of this study is to investigate if a set amount of milk-based drink is eliminated from the stomach within 4 hours of ingestion. The secondary aims are to investigate if there is a difference in gastric content after drinking low- or high-fat yoghurt, and to validate ultrasound for determining the gastric content volume after 4 hours of fasting.

### Who can participate?

Adult patients who have been referred to the Endoscopy Unit at Uppsala University Hospital for endoscopic examination of the stomach (gastroscopy)

### What does the study involve?

In the first phase of the study, 100 adults scheduled for a gastroscopy (investigation of the stomach with a fiberoptic camera) are instructed to drink one glass (250 ml) or two glasses (500 ml) of milk 4 hours before the planned procedure. During the gastroscopy, any gastric content is suctioned into a container and analysed with respect to volume and type of content (clear, milk-stained or solid content). The procedure then continues according to the clinical routine. In the second phase of the study, a different set of 100 adults scheduled for gastroscopy are instructed to drink a fixed volume of either low-fat (50 kcal/100 ml) or high-fat yoghurt (100 kcal/100 ml). The volume will be either 250 ml or 500 ml, depending on the results of the first phase of the study. The gastroscopy is carried out as for the first group above. In addition, an ultrasound examination of the stomach is performed to determine the type and estimate the volume of any residual content. This ultrasound examination is performed immediately before the gastroscopy.

### What are the possible benefits and risks of participating?

Participating in the study does not give any possible benefits. There are no known risks of participating. The gastroscopy is performed as per routine, with the exception that the initial

contents of the stomach are suctioned out at the beginning of the procedure instead of at the end. The ultrasound examination is non-invasive and painless, and poses no risks to the participant.

Where is the study run from?  
Uppsala University Hospital (Sweden)

When is the study starting and how long is it expected to run for?  
The planning of the study started in May 2018. The first inclusion of participants is planned for January 20th, 2020. The study is expected to run for approximately 12 months.

Who is funding the study?  
Uppsala University Hospital (Sweden)

Who is the main contact?  
Dr Peter Frykholm  
peter.frykholm@surgsci.uu.se

## Contact information

**Type(s)**  
Public

**Contact name**  
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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
1

## Study information

**Scientific Title**

Is gastric emptying complete 4 hours after intake of 250 or 500 ml milk or yoghurt?

**Acronym**

GMILK

**Study objectives**

Gastric emptying of 250 ml milk or yoghurt is complete within 4 hours of intake.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 18/08/2018, Uppsala Regional Ethics Committee (Box 1964, 751 49 Uppsala, Sweden; correspondence should be sent to the new Swedish Ethics Review Authority, Box 2120, 750 02 Uppsala, Sweden), ref: 2018/286

**Study design**

Prospective observational cohort study

**Primary study design**

Observational

**Study type(s)**

Diagnostic

**Health condition(s) or problem(s) studied**

Adult patients referred for gastroscopy due to gastrointestinal complaints or other symptoms

**Interventions**

In the first phase of the study, 100 adults scheduled for gastroscopy are instructed to drink one glass (250 ml) or two glasses (500 ml) of milk 4 hours before the planned procedure. During the gastroscopy, any gastric content is suctioned into a container and analysed with respect to volume and type of content (clear, milk-stained or solid content). This is the endpoint of the study, and the procedure then continues according to the clinical routine.

In the second phase of the study, a different set of 100 adults scheduled for gastroscopy are instructed to drink a fixed volume of either low-fat (50 kcal/100ml) or high-fat yoghurt (100 kcal/100ml). The volume will be either 250 ml or 500 ml, depending on the results of the first phase of the study. The gastroscopy part of the protocol is as for the first group above. In addition, an ultrasound examination of the stomach is performed to determine the type and estimate the volume of any residual content. This ultrasound examination is performed immediately before the gastroscopy.

**Intervention Type**

Other

**Primary outcome(s)**

The volume of milk-stained or solid gastric content in ml, 4 hours after ingestion of milk or yoghurt, that can be suctioned from the stomach, measured as soon as the endoscope enters the stomach

### **Key secondary outcome(s)**

1. The volume of gastric content in ml, estimated with ultrasound, 4 hours after ingestion of milk or yoghurt and immediately before gastroscopy, compared with the volume suctioned through the endoscope the first time it enters the stomach
2. The volume of gastric content in ml, 4 hours after ingestion of low-fat or high-fat yoghurt, measured as soon as the endoscope enters the stomach

### **Completion date**

01/05/2021

## **Eligibility**

### **Key inclusion criteria**

Adult patients referred for gastroscopy because of gastrointestinal symptoms

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **Key exclusion criteria**

1. Age < 18 years
2. Age > 60 years
3. Body mass index > 30
4. Condition known to be associated with delayed gastric emptying

### **Date of first enrolment**

20/01/2020

### **Date of final enrolment**

20/01/2021

## **Locations**

### **Countries of recruitment**

Sweden

Switzerland

**Study participating centre**  
Endoscopy unit, Uppsala University Hospital  
Sjukhusvägen 1  
Uppsala  
Sweden  
75185

## Sponsor information

**Organisation**  
Uppsala University Hospital

**ROR**  
<https://ror.org/01apvbh93>

## Funder(s)

**Funder type**  
University/education

**Funder Name**  
Uppsala Universitet

**Alternative Name(s)**  
Uppsala University, UU\_University, Uppsala Universitet, Sweden, UU

**Funding Body Type**  
Government organisation

**Funding Body Subtype**  
Universities (academic only)

**Location**  
Sweden

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Peter Frykholm ([peter.frykholm@surgsci.uu.se](mailto:peter.frykholm@surgsci.uu.se)). The patients have

consented to sharing anonymised data on a group level. Researchers or peer reviewers may also obtain anonymised raw data. The data will be saved up to 10 years after publication.

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>			05/02/2020	No	No