

# Does oat-based milk take longer than fruit juices to empty from the stomach?

<b>Submission date</b> 02/06/2021	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 03/06/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 27/11/2023	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Many patients are subjected to unnecessarily long fasting periods before anesthesia and surgery. Current guidelines recommend a minimum of 6 hours fasting for solid and semi-solid food such as milk or yoghurt, which usually leads to fasting overnight even if the surgery is scheduled in the afternoon. Some paediatric centers have reduced the minimum fasting time to 4 hours for a "light breakfast" of a limited amount of food. However, there is not enough evidence to determine how much food is safe with a 4 hour limit.

The primary aim is to determine if 500 mls of either oat-based drink or fruit juice is emptied from the stomach after 4 hours. The secondary aim is to investigate if oat-based drink or fruit juice of the same caloric content have similar gastric emptying rates.

### Who can participate?

Healthy adult volunteers

### What does the study involve?

Participants will ingest 500 ml of one of 4 different fluids after an overnight fast. Changes in gastric cross-sectional area are monitored repeatedly during four hours using gastric ultrasound. The volunteers will repeat the procedure for all 4 fluids in a randomised order.

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

None

### Where is the study run from?

Uppsala University Hospital (Sweden)

### When is the study starting and how long is it expected to run for?

January 2021 to March 2022

### Who is funding the study?

Uppsala University (Sweden)

Who is the main contact?

Dr Peter Frykholm, peter.frykholm@surgsci.uu.se

## Contact information

### Type(s)

Scientific

### Contact name

Dr Peter Frykholm

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

Okabereplika 1.1

## Study information

### Scientific Title

Gastric emptying of non-clear fluids: a comparison of vegetable-based milk product with iso-calorically adjusted clear fluids

### Study objectives

Gastric emptying is similar after ingestion of fluids of different composition but with the same volume and the same caloric content.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved 21/03/2021, Swedish Ethical Review Authority (Etikprövningsmyndigheten, Box 2110, 750 02, Uppsala, Sweden; +46 10-475 08 00; [registrator@etikprovning.se](mailto:registrator@etikprovning.se)), ref: #2021-00623

## Study design

Randomized cross-over single blind controlled trial

## Primary study design

Interventional

## Study type(s)

Other

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

Determination of the rate of gastric emptying of two different types of fluid in healthy volunteers

## Interventions

16 healthy volunteers will ingest 500 ml of one of 4 different fluids after an overnight fast. Changes in gastric cross-sectional area are monitored repeatedly for four hours using gastric ultrasound. The volunteers will repeat the procedure for all 4 fluids in a randomised order. The ultrasound operator is blinded to the type of fluid ingested.

Randomisation in blocks of four using the website <https://www.Randomize.org>. Each subject picks a sealed envelope that includes the order in which he will take his drinks. The envelope is opened by a researcher not involved in the ultrasound exams that particular day.

## Intervention Type

Supplement

## Primary outcome(s)

Gastric antral surface area (cm<sup>2</sup>)

Measurement method: the abdomen is scanned with a curvilinear probe, the antrum is identified in the same plane as either the aorta, the superior mesenteric artery or the lower vena cava. The image is frozen and the cross-sectional area (CSA) is delineated using the ultrasound machine's internal software application.

Measurements are taken at baseline (before ingestion of study drink), and up to 360 minutes after ingestion if needed, but until the antral CSA reaches baseline +/- 5%.

## Key secondary outcome(s)

Gastric antral surface area (cm<sup>2</sup>) measured as above at baseline and 10, 20, 30, 40, 50, 60, 100, 140, 180, 210, 240, 270, 300, 330 minutes after ingestion

## Completion date

31/03/2022

## Eligibility

### Key inclusion criteria

Healthy adults without ongoing medication or medical condition associated with delayed gastric emptying

**Participant type(s)**

Healthy volunteer

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Total final enrolment**

16

**Key exclusion criteria**

1. Diabetes
2. Gastrointestinal motility disorder
3. Pregnancy beyond the 2nd trimester
4. Medications that delay gastric emptying
5. Previous abdominal surgery
6. Morbid obesity

**Date of first enrolment**

03/06/2021

**Date of final enrolment**

03/01/2022

**Locations****Countries of recruitment**

Sweden

**Study participating centre**

**Uppsala University**

Uppsala University Hospital

Dept of Surgical Sciences

Uppsala

Sweden

752 85

**Sponsor information****Organisation**

Uppsala University

**ROR**

<https://ror.org/048a87296>

## 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**

All data generated or analysed during this study will be included in the subsequent results publication

**IPD sharing plan summary**

Other

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		25/11/2023	27/11/2023	Yes	No
<a href="#">Participant information sheet</a>			08/07/2021	No	Yes
<a href="#">Protocol file</a>			08/07/2021	No	No