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

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 02/06/2021 | No longer recruiting | [X] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 03/06/2021 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 27/11/2023 | Digestive System | |

## 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
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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
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), ref: #2021-00623

## Study design
Randomized cross-over single blind controlled trial

## Primary study design
Interventional

## Secondary study design
Randomised cross over trial

## Study setting(s)
Hospital

## Study type(s)
Other

## Participant information sheet
See study outputs table

## 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 measure
Gastric antral surface area (cm2)
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 antd 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%.

## Secondary outcome measures

Gastric antral surface area (cm2) measured as above at baseline and 10, 20, 30, 40, 50, 60, 100, 140, 180, 210, 240, 270, 300, 330 minutes after ingestion

### Overall study start date
10/01/2021

### Completion date
31/03/2022

## Eligibility

### Key inclusion criteria
Healthy adults without ongoing medication or medical condition associated with delayed gastric emtpying

### Participant type(s)
Healthy volunteer

### Age group
Adult

### Sex
Both

### Target number of participants
8 males and 8 females

### 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
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## Sponsor information

### Organisation
Uppsala University

### Sponsor details
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### Sponsor type
University/education

### Website
https://www.uu.se/en

### 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

### Publication and dissemination plan
We plan to publish the study in a peer-reviewed anaesthesiology journal.

### Intention to publish date
01/04/2023

### 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? |
|---|---|---|---|---|---|
| Participant information sheet | | | 08/07/2021 | No | Yes |
| Protocol file | | | 08/07/2021 | No | No |
| Results article | | 25/11/2023 | 27/11/2023 | Yes | No |