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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

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Additional identifiers

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), ref: #2021-00623

Primary study design
Interventional

Study design
Randomized cross-over single blind controlled trial

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 (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%.

Key secondary outcome(s)
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

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

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)
uppsalauni, Uppsala Universitet, Sweden, Uppsala University, 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?
Results article		25/11/2023	27/11/2023	Yes	No
Participant information sheet			08/07/2021	No	Yes
Protocol file			08/07/2021	No	No