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

Submission date
09/01/2020

Recruitment status
No longer recruiting

Registration date
15/01/2020

Overall study status
Completed

Last Edited
05/02/2020

Condition category
Digestive System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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 fibreoptic 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
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Available on request from the principal investigator. Available only in Swedish.

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 measure
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

Secondary outcome measures
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

Overall study start date
01/05/2018

Completion date
01/05/2021

Eligibility

Key inclusion criteria
Adult patients referred for gastroscopy because of gastrointestinal symptoms

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
200

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
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Sponsor information

Organisation
Uppsala University Hospital

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.akademiska.se/

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

Publication and dissemination plan
The results will be presented at scientific meetings and published in a peer-reviewed scientific journal in 2021

Intention to publish date
01/06/2021

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). 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?
Protocol file			05/02/2020	No	No