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A comparison of stomach volume in volunteers following two different guidelines for starvation before a general anaesthetic

Submission date
21/07/2022

Recruitment status
No longer recruiting

Registration date
25/07/2022

Overall study status
Completed

Last Edited
20/01/2023

Condition category
Other

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

Plain English summary of protocol

Background and study aims
According to current UK guidelines, people are asked to avoid drinking clear fluids for 2 hours before an operation (and to avoid solid food for 6 hours before). This is to make sure that their stomach is empty at the time of their operation because it can be dangerous if the stomach is not empty. However, it has been suggested that people should be allowed to drink clear fluids closer to the time of their operation because water leaves the stomach quickly. This could reduce the risk of someone becoming dehydrated, and reduce the likelihood of experiencing symptoms of thirst, dizziness, headache or nausea. Often a delay in the start of surgery can lead to extended periods of fasting. Some countries are already following less strict guidelines than the UK. The aim of this study is to measure how quickly a drink of water leaves the stomach of healthy people, and how much is left in the stomach after following the UK fasting guidelines and the less strict Scandinavian guidelines.

Who can participate?
Healthy volunteers aged over 18 years

What does the study involve?
Participants will be asked to fast from food for 6 hours and water for 2 hours, and then attend the Musculoskeletal Research Unit for an ultrasound examination of their stomach. In order to locate the stomach, an ultrasound probe will need to be placed on the skin around the abdomen. Therefore, it is important that suitable clothing is worn (i.e. easy to expose the abdomen). The researchers will take some basic details and then perform an ultrasound scan of the stomach. This will give us a baseline value of the area of the stomach after a period of fasting. Following this, participants will either be designated to follow a protocol of having drinks of water over a period of 2 hours, or to have no drinks at all. At various points the researchers will perform additional ultrasound scans. Participants will be asked to provide ratings of their comfort, thirst, hunger and anxiety levels at various timepoints during the session. Following the scans participants can eat and drink immediately. Participants attend on two separate days so the researchers can repeat the study with different amounts of water during the ultrasound examination.

What are the possible benefits and risks of participating?
There will not be any direct benefits to participants, but there may be potential benefits to those undergoing surgery in the future. There are no major risks of being involved. The study will only require participants to undergo a period of fasting, to drink water at set intervals and to undergo ultrasound scans. They may feel thirsty or uncomfortable during the fasting period, although the times will be kept as short as possible. Someone will monitor participants' comfort levels at all times and should they wish to stop participating they may do so at any time. Ultrasound scanning has been shown to be one of the safest medical techniques and is routinely used to scan babies, both before and after birth, children and adults. It has been widely used in clinical practice for over 40 years, providing valuable pictures and information with no evidence of any harm. However, just as ordinary sounds that are too loud can damage hearing, very high levels of ultrasound can produce undesirable effects, for example by warming the tissue through which the ultrasound passes. Because of this there are strict guidelines about the level of ultrasound that can be used. This study will operate well within these guidelines.

Where is the study run from?
The Musculoskeletal Research Unit at the University of Bristol (UK)

When is the study starting and how long is it expected to run for?
January 2015 to September 2018

Who is funding the study?
David Telling Charitable Trust (UK)

Who is the main contact?
Dr Chris Thompson, at17585@bristol.ac.uk

Contact information

Type(s)
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
238262

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
49141, IRAS 238262

Study information

Scientific Title

A randomised trial of ultrasonographic assessment of gastric emptying following water ingestion in healthy volunteers

Study objectives
It is hypothesised that water leaves the stomach rapidly and that ultrasound can be used to assess this when healthy volunteers have followed either current UK guidelines for fasting before anaesthesia, or a more liberal fluid regime (Scandinavian guidelines).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/05/2017, University of Bristol Faculty of Health Sciences Research Ethics Committee (University of Bristol Faculty of Health Sciences, First Floor South, Senate House, Tyndall Avenue, Bristol, BS8 1TH, UK; +44 (0)117 331 8197, +44 (0)117 928 9089; Liam.McKervey@bristol.ac.uk), ref: 49141

Study design
Single-centre interventional single-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Gastric volume after following two different guidelines for starvation prior to general anaesthetic

Interventions
Participants are allowed clear fluids but no solid food for the first 4 hours of the study, and for the next 2 hours before the theoretical time of induction of anaesthesia (time zero) they are randomised to either a nil-by-mouth ‘control’ group or an ‘H_2O’ group (150 ml of water each hour). Participants are randomised by opening sequential envelopes.

Gastric volume is measured by ultrasound every 30 minutes during the 2-hour study period in which participants were at the study location, with measurements taken both immediately before and after intervention (either consuming water or remaining fasted). A minimum of seven measurements are made. In the event that gastric volume has not returned to baseline volume by the end of each protocol further ultrasound scans are conducted for up to an additional 2 hours.

Ultrasound scans are performed by four qualified NHS sonographers (PG Diploma - Medical Ultrasound) trained in gastric ultrasound using a Sonosite X-Porte ultrasound machine with a curvilinear 2-5 MHz probe (FUJIFILM Sonosite Limited, UK). Assessment of gastric volume is made by measuring the gastric antral cross-sectional area (CSA) using the method described on https://www.gastricultrasound.org, with permission from the authors. Scanning is performed with the participant in the right lateral decubitus position, with minimal probe pressure and images acquired at the end of normal tidal volume expiration. The cross-sectional area of the

antrum is calculated by the sonographer using a free-hand tracing technique. Gastric volume is calculated as follows: Gastric Volume (ml) = 27.0 + 14.6 x right-lateral CSA (cm^2) – 1.28 x age (yr)

Intervention Type
Other

Primary outcome(s)
Total gastric volume at time zero. Gastric volume is measured by ultrasound every 30 minutes during the 2-hour study period in which participants were at the study location, with measurements taken both immediately before and after intervention (either consuming water or remaining fasted). A minimum of seven measurements are made. In the event that gastric volume has not returned to baseline volume by the end of each protocol further ultrasound scans are conducted for up to an additional 2 hours.

Key secondary outcome(s))
Wellbeing scores: quantitative data on thirst, hunger and anxiety scores collected using a simple numeric interval scale of 1 to 10 developed for this study at t-120, t-60 and t0

Completion date
29/09/2018

Eligibility

Key inclusion criteria
1. Adults aged 18 years or over
2. Able to follow the protocol
3. Able to attend on two separate days

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
15

Key exclusion criteria
1. Pregnancy
2. Taking medication that may influence appetite or gastric physiology
3. Any medical condition which alters appetite or gastric physiology, e.g. previous gastro-

duodenal surgery
4. Diabetes mellitus
5. Advanced liver or renal disease
6. Recent gastrointestinal infection (within 1 month)
7. Any condition that hinders the acquisition of ultrasound images

Date of first enrolment
26/05/2018

Date of final enrolment
29/09/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Bristol Musculoskeletal Research Unit
Learning and Research Centre
Southmead Hospital
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Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Charity

Funder Name

David Telling Charitable Trust

Alternative Name(s)
THE DAVID TELLING CHARITABLE TRUST

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The anonymised data are available at the University of Bristol data repository (data.bris) at https://doi.org/10.5523/bris.10ejjx7clm1x728dw0w5xxcydy. Further information is available at https://www.bristol.ac.uk/staff/researchers/data/

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Dataset		13/08/2020	25/07/2022	No	No
Participant information sheet	version 1	14/02/2017	25/07/2022	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Preprint results		26/07/2022	20/01/2023	No	No
Protocol file	version 6	01/02/2017	15/08/2022	No	No