Stomach contents with the aid of ultrasound in healthy volunteers

Published: 06-06-2016
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The purpose of this study is to examine in healthy volunteers or the research results can be reproduced for the measurement of the stomach contents in our center. It is not the aim to validate the formula of Perlas et al.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON43363

Source
ToetsingOnline

Brief title
EchoM

Condition

- Other condition

Synonym
gastric contents

Health condition

Maaginhoud

Research involving
Human

Sponsors and support

Primary sponsor: Isala klinieken
Source(s) of monetary or material Support: Geen

Intervention

Keyword: Stomach contents, Ultrasound

Outcome measures

Primary outcome

The primary outcome is the area of the stomach in cm2

Secondary outcome

nvt

Study description

Background summary

The introduction in giving general anesthesia is one of the moments with the greatest risk of complications. One of the possible complications is the aspiration of gastric contents. Setting a period of fasting before undergoing general anesthesia has reduced this risk. This is not possible for acute for emergency interventions. In addition, having pain and analgesia can have a negative effect on emptying of the stomach. Would it be possible to use the echo to produce a reliable measure for estimating the stomach contents?

Perlas et al. carried out several studies for the measurement of the gastric content for elective surgery. It has been shown that the measurement of the antrum of the stomach corresponds the best to the actual stomach contents.

Study objective

The purpose of this study is to examine in healthy volunteers or the research results can be reproduced for the measurement of the stomach contents in our center. It is not the aim to validate the formula of Perlas et al.

Study design

The research design of this pilot study is a prospective observational study.

The study population consists of healthy volunteers of at least 18 years old.
The primary outcome measure is the surface area of the antrum of the stomach, which could be compared with the amount of food ingested. The surface area is determined with the aid of an echo.

Study burden and risks

The burden for the subjects consists only of time and to be sober before undergoing ultrasound examination. Volunteers must drink 2x 250 ml of water and ingest a solid meal.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- 18 years or older
- ASA (anesthesiologists physical status classification) classification I or II
- Volunteers must be able to understand the study protocol and to give informed consent

Exclusion criteria

- Volunteers who are at risk of a enlarged stomach or delayed gastric emptying, (pregnancy, diabetes, history of reflux disease, other disorders of the stomach / esophagus, history of surgery on the upper part of the digestive tract).
- Volunteers who are not able to understand the study protocol and to give informed consent

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-07-2016
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	06-06-2016
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL57413.075.16