

The incidence and clinical implications of "full stomach" in an elective surgical population. An observational study using bedside sonography.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24657

Source

Nationaal Trial Register

Health condition

aspiration, ultrasound, gastric, full stomach

Sponsors and support

Primary sponsor: UMC Radboud, Nijmegen the Netherlands

Source(s) of monetary or material Support: UMC Radboud, Nijmegen the Netherlands

Intervention

Outcome measures

Primary outcome

Incidence of "full stomach" despite following standard Fasting instructions for elective surgical procedures

Secondary outcome

Aspiration

Probable intra-operative aspiration

aspiration pneumonitis/pneumonie

ARDS, pneumonie, ALI, death

Study description

Background summary

The incidence and clinical implications of “full stomach” in an elective surgical population. An observational study using bedside sonography

Summary

Introduction

Pulmonary aspiration of gastric content is a serious perioperative complication associated with significant morbidity and mortality.

Bedside Gastric ultrasonography (GUS) is a non-invasive tool that provides both qualitative and quantitative information about gastric contents.

The primary aim of this observational study is to determine the proportion of patients that present for elective surgical procedures with a “full stomach” despite following standard fasting instructions

A secondary objective is to evaluate common respiratory outcomes in this subset of patients who undergo elective surgery with a “full stomach”.

Methods

All patients 18 years of age or older, scheduled for elective surgery under either regional or general anesthesia will be included. Exclusion criteria will be: pre-existing structural abnormality of the upper gastro-intestinal tract (e.g. previous lower esophageal or gastric surgery, hiatal hernia, gastric cancer), pregnancy and emergency surgery. An observational study during a two-year period.

On the surgical date a complete medical history and demographic data will be registered. A focused ultrasound examination of the stomach will be performed. The nature of the content (none, clear fluid or thick fluid/solid) will be documented based on qualitative sonographic features. For clear fluids, a previously described 3-point grading system will be used.

No further evaluations will be performed in subjects with an “empty stomach”. Conversely, a more detailed gastric ultrasound examination will be performed on all patients with a “full stomach” and they will be followed prospectively for 7 days to document respiratory outcomes.

Data management

All data will be gathered prospectively and documented in writing. Data will be summarized using descriptive statistics. Count and percentages will be used for categorical variables, and mean and standard deviation for continuous variables

Study objective

To determine the proportion of patients that present for elective surgical procedures with a "full stomach" despite following standard Fasting instructions

Study design

Primary outcome is pre-operative

Secondary outcome is intra-operative AND first 7 days post-operative

Intervention

Pre-operative a focused ultrasound examination of the stomach in supine and right lateral decubitus position.

Contacts

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Eligibility criteria

Inclusion criteria

18 years of age or older, scheduled for elective surgery under either regional or general anaesthesia.

Exclusion criteria

pre-existing structural abnormality of the upper gastro-intestinal tract, pregnancy and emergency surgery

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	15-06-2017
Enrollment:	0
Type:	Anticipated

Ethics review

Positive opinion

Date: 06-06-2017

Application type: First submission

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
NTR-new	NL6330
NTR-old	NTR6522
Other	: 2015-2010

Study results