Assessment of gastric contents in elective paediatric surgery.

No registrations found.

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

Summary

ID

NL-OMON29582

Source
NTR

Brief title
PedGUS

Health condition

NA

Sponsors and support

Primary sponsor: Department of Anaesthesiology, Radboudumc
Source(s) of monetary or material Support: Department of Anaesthesiology, Radboudumc

Intervention

Outcome measures

Primary outcome

Total gastric fluid volume (quantitatively and qualitatively) in children scheduled for elective surgery after the liberal 6-4-0 regime.

Secondary outcome

- Prevalence of solid contents and/or a calculated gastric fluid volume >1.5 mL/kg
- Actual duration of fluid fasting in daily clinical practice with the 6-4-0 regime

Study description

Background summary

Rationale:
The current guidelines for perioperative fasting in paediatric patients recommend 6 h for solids, 4 h for breast milk, and 2 h for clear fluids prior to anaesthesia (6-4-2 regime). In Sweden a more liberal fasting regime has been implemented for more than a decade. Children scheduled for elective procedures requiring anaesthesia are allowed to drink clear fluids until they are called to the operating room (6-4-0) regime. Increased gastric content volume is one of the contributing factors for regurgitation and pulmonary aspiration.

Objective:
Estimate the total gastric volume quantitatively and determine qualitatively gastric contents by gastric ultrasound after the implementation of the liberal 6-4-0 h regime.

Study design:
A prospective observational study.

Study population:
Paediatric patients up to sixteen years of age for elective surgery

Intervention (if applicable): NA

Main study parameters/endpoints:
To assess the total gastric volume quantitatively and qualitatively with paediatric patients after implantation of the liberal (6-4-0) regime for fasting.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
By using a non-invasive instrument and minimizing the duration of the research to a few minutes with every patient we try to minimize the potential risk and burden.

Study objective

Gastric fluid volumes in patients with a 6-4-0 pre-operative fasting regime are comparable to patients with a 6-4-2 pre-operative fasting regime

Study design

One-time measurement, directly pre-operatively

Intervention

NA (Observational)

Contacts

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Eligibility criteria

Inclusion criteria

- Age between 0 and 16 years
- Elective surgery
- Followed the fasting guidelines with the 6-4-0 regime
- Informed consent

Exclusion criteria

- Refusal of parents or legal guardian to participate in the study
- History of upper gastrointestinal disease or surgical procedures of the esophagus or the upper abdomen
- Emergency surgery
- Pre-existing structural abnormality of the upper gastro-intestinal tract
- Decision of the care providers that the ultrasound examination is not in the best interest of the patient at that time

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2022
Enrollment:	200
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	06-09-2021
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	NL9716
Other	CMO Radboudumc : CMO 2020-6924

Study results