

Assessment of gastric contents in elective paediatric surgery.

Gepubliceerd: 06-09-2021 Laatste bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON29582

Bron

NTR

Verkorte titel

PedGUS

Aandoening

NA

Ondersteuning

Primaire sponsor: Department of Anaesthesiology, Radboudumc

Overige ondersteuning: Department of Anaesthesiology, Radboudumc

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

One-time measurement, directly pre-operatively

Onderzoeksproduct en/of interventie

NA (Observational)

Contactpersonen

Publiek

Radboudumc
Tristan van Leest

024 361 1111

Wetenschappelijk

Radboudumc
Tristan van Leest

024 361 1111

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-03-2022
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	06-09-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9716
Ander register	CMO Radboudumc : CMO 2020-6924

Resultaten