Recording and evaluating preoperative fasting times at the AUMC, location AMC

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28268

Source
Nationaal Trial Register

Brief title
Fasting

Health condition

surgical patients

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

- To study the average preoperative fasting times for elective surgical patients at the AUMC, location AMC.
- To study the incidence of prolonged fasting, defined as longer than the standard fasting times preoperatively (6-2 hrs rule for adults, 6-4-1 hrs rule for children).

And, separately, record the preoperative fasting times for the following food categories:
- of solids
- of clear fluids
- of and in case of children (non-)human milk

Secondary outcome

- Study the differences in fasting times between surgical specialties / surgical wards.
- Study the differences in fasting times between clinical surgery's and day case surgery's.
- Study the differences in fasting times between the first scheduled patient of the day and the other scheduled patients.
- Study the patient characteristics that are associated with the preoperative fasting times?

Study description

Background summary

Preoperative fasting is a standard procedure for every patient having surgery. Patients are fasted preoperatively to prevent regurgitation and aspiration of gastric contents during anesthesia. Normally, our airway protective reflexes (gagging, coughing and swallowing) prevent regurgitated gastric content from entering the lungs. These protective reflexes are reduced during general anesthesia and could lead to pulmonary aspiration when regurgitation occurs. The majority of aspirations occur at the induction and/or emergence of anesthesia, e.g during laryngoscopy at induction (32.9%) and/or tracheal extubation at emergence (35.9%) from anesthesia.

Historically, preoperative patients would fast from midnight, but the ASA overturned this practice in 1999 by demonstrating that shortened fasting times did not significantly increase the risk of adverse outcomes. More recent studies have shown that prolonged preoperative fasting is associated with dehydration, hypoglycaemia, electrolyte imbalance and reduced patient comfort. Minimizing perioperative fasting has been developing progressively, with modern fasting times set as the 6-2 rule for adults and the 6-4-1 rule for children (the rules are explained in the next paragraph). These are published in different international and national guidelines (e.g. the ESA guideline, ASA guideline, ESPA guideline and the ESPEN guideline) and apply to patients having elective surgery under general anesthesia, regional anesthesia or monitored anesthesia.

The 6-2 rule for adults means that one can eat food until 6 hours preoperatively and drink clear fluids until 2 hours preoperatively. The 6-4-1 rule for children means eating food and/or drinking non-human milk until 6 hours preoperatively, drinking human milk until 4 hours preoperatively and drinking clear fluids until 1 hour preoperatively. However, adherence to the guidelines is still difficult and it is shown that patients tend to overfast.

Also at the AUMC, location AMC, the 6-2 and the 6-4-1 rules seem difficult to follow, but a fact

finding is not done yet. A thorough baseline measurement of preoperative fasting times, which is the aim of the current study, is needed before starting to implement or alter strategies to improve adherence to the preoperative fasting guidelines.

Study objective

Recording and evaluating the preoperative fasting times at the AUMC, location AMC, will lead to insight on the actual preoperative fasting times, provide insight into co-variables of prolonged preoperative fasting times, and help us to determine relevant parameters to make strategies to improve implementation of the current guidelines on preoperative fasting.

Study design

Start of study: 9-9-2020

Time points for primary outcomes:
- Via a short questionnaire the patients are directly asked about their preoperative fasting times at the waiting room (holding) of the theatre complex just before surgery
- The planned time of the start of surgery will be retrieved from the schedule at the electronic patient file (which is in EPIC at the AMC) the day before surgery
- The data are collected in a Castor EDC database, and are analysed using the SPSS program.
- The data average preoperative fasting time will be given as a mean with a 95% confidence interval.
- The incidence of prolonged fasting will be given as a percentage.

Time points for secondary outcomes:
- The patient characteristics are retrieved from the EPIC files of the patients preoperatively
- The other study parameters of the secondary outcomes will be retrieved for the EPIC files of the patients postoperatively
- These data are collected in the same Castor EDC database as the primary outcomes, and are analysed using the SPSS program.
- The differences in fasting times between surgical specialties/surgical wards will be analysed by one-way ANOVA with Levene's test for equality of variance and presented as a mean with a standard deviation.
- The differences in fasting times between clinical surgery's and day case surgery's will be analysed by unpaired t-test and presented as a mean with a standard deviation.
- The differences in fasting times between the first scheduled patient of the day and the other scheduled patients will be analysed by multivariate linear regression and defined by an adjusted R square, a F-test and unstandardized coefficients.
- The patients characteristics that might be associated with the preoperative fasting times will be analysed by t-tests, one-way ANOVA, and single linear regression.

Intervention

none

Contacts

Public
Amsterdam University Medical Centres, location AMC
Mireille van Stijn

0205669111 pager 29428
Scientific
Amsterdam University Medical Centres, location AMC
Mireille van Stijn

0205669111 pager 29428

Eligibility criteria

Inclusion criteria

- Patients scheduled for elective surgery at the operating theaters of the AUMC, location AMC
- Patients receiving general anesthesia, (loco)regional anesthesia or requested monitoring by an anesthesia team

Exclusion criteria

- Patients for emergency surgery
- Patients admitted at the Intensive Care Unit preoperatively
- Patients who completed and send back the no objection letter

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:	Recruiting
Start date (anticipated):	09-09-2020
Enrollment:	1004
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Not applicable

Application type:	Not applicable

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	NL8999
Other	METC AMC : W20_303 # 20.338

Study results