The effects of glucagon-like peptide-1 receptor agonists on gastric emptying after preoperative fasting.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

Summary

ID

NL-OMON57391

Source
ToetsingOnline

Brief title
GALACTIC

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Gastrointestinal motility and defaecation conditions

Synonym
delayed stomach emptying, gastroparesis

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: diabetes mellitus, gastric emptying, GLP-1 receptor agonists, preoperative fasting.

Outcome measures

Primary outcome

Difference in gastric volume in ml/kg, measured by gastric ultrasound (GU), between preoperative anaesthesiology visit (GU1, while using GLP-1 RA) and before surgery (GU2, after withholding GLP-1 RA). Patients are required to fast before both GU according to the perioperative protocol (6 hours for solids, 2 hours for clear liquids).

Secondary outcome

Difference for the incidence of residual gastric content (RGC), defined as >1.5ml/kg fluids or presence of solids, between GU2 and GU1.

Difference in fasting blood glucose concentration comparing GU2 and GU1.

Study description

Background summary

There is evident success with glucagon-like-peptide-1 receptor agonists (GLP-1 RA) in the treatment for patients with diabetes mellitus type 2 (DM2). However, GLP-1 RA are also known for their gastric effects, including delayed gastric emptying. This could lead to increased residual gastric content after preoperative fasting times, which is why the current standard of care is to withhold GLP-1 RA for at least one dose before surgery. Stopping GLP-1 RA could negatively influence patients* blood glucose values resulting in an increased risk of postoperative complications and lead to logistical problems. It is argued that after more than 12 weeks of treatment with GLP-1 RA, the concerns for increased residual gastric content should be minimal as a result of tolerance and tachyphylaxis, but evidence is lacking.

Study objective

The primary objective is to evaluate the effect of continuing GLP-1 RA on gastric volume after standard preoperative fasting in patients using GLP-1 RA for >12 weeks. Additionally, we will evaluate the effect of withholding GLP-1 RA on fasting blood glucose values.

Study design

A self-controlled, non-inferiority study.

Study burden and risks

The burden of this study for participants are minimal, as patients receive two non-invasive gastric ultrasounds and blood glucose measurements by skilled professionals. Patients do not change their medication other than following standard pre-operative guidelines. The fasting on the day of preoperative visit is expected to have very minimal risks for the participants. There is no group-related burden, as the design of this study is self-controlled.

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

- Adult patients (>18 years of age)
- Using GLP-1 RA, with a treatment duration over 12 weeks.
- Undergoing planned, elective surgery under general anaesthesia
- Willing and able to provide informed consent, after adherence to standard preoperative fasting times

Exclusion criteria

- Female who is pregnant or breast-feeding
- Patients with an indication for rapid sequence induction and intubation (RSII), related to gastric emptying, such as:
o A history of gastroparesis, achalasia, or neuromuscular disorders
o Gastric outlet obstruction
o Hiatus hernia
o History of oesophageal cancer or stricture
o Previous upper gastrointestinal or bariatric surgery
o Ascites
o Small bowel obstruction

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2025
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO Date:	03-04-2025
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL87918.018.25
Other	volgt