

The effects of hiatal hernia repair and fundoplication on gastric emptying: a pilot study

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON42596

Source

ToetsingOnline

Brief title

Antireflux surgery and gastric emptying

Condition

- Other condition
- Gastrointestinal motility and defaecation conditions
- Gastrointestinal therapeutic procedures

Synonym

Delayed gastric emptying

Health condition

middenrifbreuk

Research involving

Human

Sponsors and support

Primary sponsor: Meander Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Antireflux surgery, Gastric emptying, GERD, Reflux disease

Outcome measures

Primary outcome

Gastric emptying scintigraphy (gastric retention at 0,1,2, and 4h, gastric emptying speed (T*) and lag phase duration)

Secondary outcome

- Quality of Life
- Patient satisfaction
- Subjective DGE symptoms
- Vagal nerve identification intra-operatively
- Duration of surgery in minutes
- Hiatal hernia size in cm
- % peristaltic esophageal contractions
- LES pressure in mmHg
- Nadir LES relaxation pressure in mmHg

Study description

Background summary

The normal physiology of the stomach is complicated and not yet fully

understood. Delayed gastric emptying (DGE) occurs in approximately 4% of the worldwide population. The third (after diabetes and idiopathic) most common cause is post surgical. The most common symptoms of delayed gastric emptying are nausea, vomiting, postprandial fullness and pain, early satiety and bloating. DGE is a very common complication that is accompanied by a very low quality of life. There is no evidence about whether or not gastric emptying is improved or worsened after HH repair and fundoplication. Also, there is no agreement if fundoplication is a cause of or a solution for DGE.

Study objective

The aim of this monocenter observational pilot study is to determine the incidence and severity of gastric emptying disorders in patients with a hiatal hernia and to observe the effects of hiatal hernia repair and fundoplication on the gastric emptying.

Study design

This is a prospective monocenter observational pilot study that investigates the incidence and severity of gastric emptying disorders and the effects of surgical management in patients with hiatal hernia in two cohorts: small (<3cm) and large (≥3cm) hiatal hernia. This observational study will be conducted at the Meander Medical Center in the Netherlands. Patients will be included during a six-month period and will be followed for a minimum of 12 months.

Study burden and risks

This study is associated with a neglectable risk to the subjects' wellbeing. All test subjects will undergo 2 gastric emptying studies (scintigraphy). The annual acceptable dose for workers that may be exposed to radiation is 20mSv per annum. Each scintigraphy delivers a radiation dosage of 0,2mSv. A radiation dosage that has no evident effect on the risk of getting cancer.

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

- Objectively proven GERD (by gastroscopy and/or 24-hour pH and/or impedance monitoring)
- Age ≥ 18

Exclusion criteria

- BMI ≥ 30
- Pregnancy
- Achalasia
- Previous gastric surgery
- Previous esophageal surgery
- Inability to understand the Dutch language
- Inability to understand and/or fill in the questionnaires

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-10-2015
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO	
Date:	28-09-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	22-02-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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

CCMO

ID

NL54468.100.15