Laparoscopic fundoplication for gastroesophageal reflux disease: A prospective study on reflux control and gastroesophageal motility

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Main questions:1. What is the success rate of antireflux surgery in children (reflux control) measured by means of validated and standardised investigation techniques?2. What is the effect of antireflux surgery on gastro-esophageal motility/function…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Observational non invasive

Summary

ID

NL-OMON38094

Source
ToetsingOnline

Brief title
Antireflux surgery in pediatric GERD patients

Condition

- Gastrointestinal motility and defaecation conditions
- Gastrointestinal therapeutic procedures

Synonym
reflux disease, vomiting

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Children, Fundoplication, Reflux

Outcome measures

Primary outcome

1. Percentage of failed antireflux procedures

- percentage time pH <4 (total time > 4%)

- amount of reflux episodes/24hr (> 9)

- amount of reflux episodes longer than 5 minutes (> 4)

- symptom scores (symptoms >= moderate-severe and/or daily-weekly)

2. gastroesophageal function/motility

- lower esophageal sphincter relaxation (% complete relaxation)

- percentage peristaltic contractions esophagus (%)

- contractions proximal/mid/distal esophagus (mmHg)

- gastric half-emptying time (min)

- proximal gastric adaptive relaxation (ml)

Success is defined as

a. complete symptom relief and normalised pH metry

b. complete symptom relief and near-normal pH metry

c. normalized pH metry and significant improvement of reflux symptoms

(complaints less than mild/monthly)

Secondary outcome

NA

Study description

Background summary

Antireflux surgery is one of the most common major operations performed in pediatric patients. Most studies on the outcome of antireflux surgery in children are limited to retrospective data, case reports or are based solely on symptoms.
A prospective pilot study by van der Zee, pediatric surgeon Wilhelmina Children's Hospital, University Medical Center Utrecht showed that asymptomatic patients after antireflux surgery still had pathological reflux as measured by pH metry.
To determine the outcome of antireflux surgery in children, it is essential to objectively measure reflux before and after surgery. Van der Zee also showed that 15% of failures after antireflux surgery were associated with severe gastroduodenal dysmotility. Therefore, it is essential to objectively measure the effects of antireflux surgery on gastroesophageal function and subsequently evaluate if specific features of gastroesophageal function associated with failed antireflux surgery can be identified during preoperative screening.
Studies on adult GERD patients showed that proximal gastric dilatation may play an important role in triggering gastroesophageal reflux. Proximal gastric dilatation was measured by invasive methods. Nowadays, it is possible to measure this proximal gastric function in children by non-invasive 3D-ultrasound of the stomach.

Study objective

Main questions:
1. What is the success rate of antireflux surgery in children (reflux control) measured by means of validated and standardised investigation techniques?
2. What is the effect of antireflux surgery on gastro-esophageal motility/function?
3. Are there determinants associated with failed antireflux surgery that can be identified during preoperative screening (risk stratification)?

Additional question:
4. Can innovative, non-invasive 3D-ultrasound of the stomach offer additional value in the evaluation of the effect of antireflux surgery on gastroesophageal function?

5. Study the effect of antireflux surgery on health-related quality of life

Study design

A prospective, observational cohort study on children aged 0-18yrs being considered for antireflux surgery

Methods

- before operation and 3-4 months after operation the following questionnaires will be performed:
* standardised reflux questionnaire
* Health-related Quality of Life questionnaire

- before operation and 3-4 months after operation the following investigation techniques will be performed:
* manometry and 24-hr pH metry/impedance monitoring
* 13C-octanoic acid breath test (gastric emptying)
* 3D-ultrasound of the stomach

- all patients will undergo a laparoscopic fundoplication

Study burden and risks

The current manometry, pH metry and 13C breath test are standard investigation techniques for the evaluation of reflux disease. Impedance monitoring and 3D-ultrasound of the stomach are additional investigation techniques. These investigation techniques are not associated with any additional risk for the patients.
The burden for patients is minimal because:

1. impedance: the current, smaller pH catheter is now equipped with impedance monitoring. Therefore, there is no additional burden for the patient (only additional data to be analysed by the researcher).

2. 3D ultrasound of the stomach: it is a short-lasting (30min) investigation technique during which a fluid meal (300ml/m2 body surface area) is ingested followed by non-invasive measurements of gastric volume and emptying every 5 minutes (in between measurements patients can watch tv/walk around/play). This is the only non-invasive investigation technique that can measure proximal gastric function in children.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Children (0-18 years) with gastroesophageal reflux disease (GERD) in whom
1. antireflux surgery is indicated by a pediatrician/pediatric gastroenterologist and
2. therapy-resistent or recurrent pathological gastroesophageal reflux is proven and
3. written informed consent can be obtained (In patients <12 yrs and/or who are mentally disabled, informed consent will be obtained from the parents/legal guardian. In patients >12 yrs and mentally able, informed consent will be obtained from the parents/guardians and patients themselves)

Exclusion criteria

- Inability to undergo investigation
- prior esophageal and/or gastric surgery, except gastrostoma

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-08-2011
Enrollment:	55
Type:	Actual

Ethics review

Approved WMO Date:	09-06-2009
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	01-02-2011
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	09-08-2011
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	08-11-2012

Application type:	Amendment
Review commission:	METC NedMec

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	NL22977.041.08