Developing an evidence-based guideline for the diagnosis and surgical treatment of children with severe gastro-esophageal reflux disease.

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Ethical review	Not approved
Status	Will not start
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Observational invasive

Summary

ID

NL-OMON32225

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: divisie Heelkundige Specialismen en divisie Kinderen (kindergastroenterologie) UMC Utrecht

Intervention

Keyword: Children, Fundoplication, Reflux

Outcome measures

Primary outcome

- Determining the pediatric patients with severe esophagogastric motility

disorders, prone to failure after laparoscopic antireflux surgery during the

preoperative work-up for GERD.

- Increase in succesrate of laparoscopic antireflux surgery in pediatric GERD

patients by improving selection criteria of these patients.

Secondary outcome

none

Study description

Background summary

Laparoscopic antireflux surgery (ARS) is one of the most common major operations performed in pediatric patients. However, no prospective clinical trials, in particular with use of investigative techniques, have been published. Most studies are retrospective, case reports or evaluate ARS based solely on symptoms. Data on the efficacy of laparoscopic ARS in children has shown that although nearly 90% of patients had become asymptomatic, 25% still had pathological reflux during pH monitoring. Factors determining the success rate of laparoscopic ARS in pediatric GERD, are not completely understood. However, based on a pilot study esophagogastric motility disorders seemed to be associated with failure of ARS.

Study objective

Developing an evidence-based guideline for the diagnosis and surgical treatment

of children with severe gastro-esophageal reflux disease.

Study design

Observational research:
- prospective clinical trial, comparing data before and after laparoscopic antireflux surgery

Study burden and risks

1. The impedance analysis/manometry are performed simultaneously with the standard 24pH metry (therefore, no additional burden for the patient).
2. The 13C-breath test is not associated with any risks and the burden is minimal since patients only have to consume a small meal (one pancake or glass of milk) followed by non-invasive sampling of small amount of exhalation.
3. The 3D-ultrasound is not associated with any risks and the burden is minimal since patients only have to consume a small amount of a liquid meal (Nutridrink) followed by non-invasive measurement of the gastric volume and emptying every 5 minutes during a 30-minute period (in between measurements patients can watch television/walk around).

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

Pediatric patients with severe GERD referred for antireflux surgery

Exclusion criteria

Inability to undergo investigation

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	59
Type:	Anticipated

Ethics review

Not approved

Date:	17-03-2008
Application type:	First submission

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL21620.041.08