Laparoscopic Thal fundoplication in children: A very long-term follow-up study.

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Study the very long-term efficacy (regarding reflux control) of antireflux surgery in children with severe GERD.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	Observational invasive

Summary

ID

NL-OMON36744

Source
ToetsingOnline

Brief title
Very long-term follow-up after antireflux surgery in children

Condition

- Gastrointestinal inflammatory conditions

Synonym
heartburn, reflux disease

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

Long term success of laparoscopic Thal fundoplication in children with severe

GERD:

1. Complete symptom relief and normal pH metry

2. Complete symptom relief and near-normal pH metry

3. Normal pH metry and significant improvement of reflux symptoms (complaints

less than mild/monthly)

Secondary outcome

NA

Study description

Background summary

Gastroesophageal reflux disease (GERD) is a major healthcare problem affecting the gastrointestinal tract of infants and children as well as adults. The choice of therapy for GERD depends on the severity of the disease. Moderate cases are treated with antireflux medication, whereas antireflux surgery (ARS) is reserved for severe GERD patients. In 1998 a prospective pilot study by Van der Zee et al, showed that although 90 percent of a patients were asymptomatic after ARS, 25 percent still had pathological reflux as measured by pH metry. Long-term efficacy of ARS has never been investigated prospectively. Recently, an increased incidence of reflux complaints was detected in the patient population that was published in 1998. In up to 33 percent of these patients reflux complaints were present 10-15 years after ARS. Considering that there was a significant discrepancy between reflux symptoms and objective pH monitoring after short-term follow-up, it is conceivable that even a larger percentage of patients will have objective pathological reflux 10-15 years after ARS. Therefore, it is essential to objectively measure the efficacy of

antireflux surgery on gastroesophageal reflux 10-15 years after ARS.

Study objective

Study the very long-term efficacy (regarding reflux control) of antireflux surgery in children with severe GERD.

Study design

A prospective, very long-term follow-up study on gastroesophageal reflux 10 to 15 years after antireflux surgery for severe GERD.

Methods:
All patients will undergo a 24-hour pH monitoring 10-15 years after laparoscopic Thal fundoplication.

Study burden and risks

The risk of the investigation technique for adults and children is negligible.
The 24-hour pH monitoring is currently the standard investigation technique for evaluation of reflux disease.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All patients, who have undergone laparoscopic Thal fundoplication from 1993 until 1998 for severe GERD and were prospectively included in a longitudinal study on efficacy of ARS. In all patients written consent has to be obtained.

Exclusion criteria

Inability to undergo investigation (patients in whom medication affecting gastric motility and gastroesophageal reflux cannot be stopped).

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-08-2011
Enrollment:	45

Type:	Actual

Ethics review

Approved WMO Date:	02-05-2011
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	NL35380.041.11