Gastric Emptying in children with a gastrostomy.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28523

Source
Nationaal Trial Register

Health condition

Laproscopic gastrostomy, gastric emptying, gastro-oesophageal reflux disease (GERD), children

Sponsors and support

Primary sponsor: University Medical Center Utrecht (UMCU)
Source(s) of monetary or material Support: NutsOhra Zorgsubsidies

Intervention

Outcome measures

Primary outcome

1. To determine the effect of LGTP on gastric emptying in children, by comparing gastric emptying half time (T½) before and after operation;

2. To identify predictors (gastric emptying) for success of a gastrostomy placement.

Secondary outcome

1. To determine the influence of a gastrostomy placement on gastroesophageal reflux;

2. To determine the effect of a gastrostomy on quality of life.

Study description

Background summary

Laparoscopic gastrostomy tube placement (LGTP) is a frequently performed procedure to benefit pediatric patients with severe feeding difficulties. Most of these patients have significant neurologic impairment. In most children a LGTP is successful, because in time adequate caloric intake can be obtained through the gastric tube. Nevertheless, in 10% of patients a LGTP fails. Some believe that failure could be related to pre-existent delayed gastric emptying. However, this is not based on clinical evidence. An alternative route of enteral feeding is a laparoscopic jejunostomy tube placement (LJTP). A LJTP bypasses the stomach and is therefore hypothesised as a treatment of first choice in children with severe delayed gastric emptying, by some. However, a jejunostomy has major drawbacks. First, after a LJTP, all children are dependent on continues drip feeding, whereas with a LGTP it is possible to administer feedings in portions (bolus). Furthermore, complications as dislocation, obstruction, infection and adhesion ileus are more frequently seen after a LJTP. Gastric emptying studies have never been performed before and after LGTP in children. If a LGTP would lead to a significant increase in gastric emptying, there would be no reason to consider a gastrostomy contraindicated in patients with severe delayed gastric emptying. Subsequently, jejunostomy tubes need not be placed directly in patients with severe delayed gastric emptying.

Another issue concerning gastrostomy placements is that an increase of gastroesophageal reflux (GER) symptoms after gastrostomy placement is often described in scientific literature. GER is a passive flow of gastric (acidic) contents into the esophagus. However, only a few studies have used objective 24-hour monitoring to evaluate GER after gastrostomy placement. An increase in GER in these studies was not found, which could be explained by the fact that the studied patient population was too limited.Well-designed prospective studies using objective 24-hour pH monitoring in combination with reflux symptom severity scores are lacking.

Objective:

1. To determine the effect of LGTP on gastric emptying in children, by comparing gastric emptying half time (T½) before and after operation;

2. To identify predictors (gastric emptying) for success of a gastrostomy placement;

3. To determine the influence of a gastrostomy placement on gastroesophageal reflux;

4. To determine the effect of a gastrostomy on quality of life.

Study design:

A prospective, observational cohort study in children aged 2-18yrs, undergoing LGTP.

Study population:

All children (2-18yrs), who are being considered for LGTP in the Wilhelmina Children's Hospital, University Medical Center Utrecht.

Main study parameters/endpoints:

1. 13C octanoic acid breath test: Gastric halftime;

2. 24-hour pH-impedance monitoring: Total acid exposure time/ symptom association probability;

3. HRQoL questionnaire: total score.

Study objective

Laparoscopic gastrostomy tube placement (LGTP) is a frequently performed procedure to benefit pediatric patients with severe feeding difficulties. Most of these patients have significant neurologic impairment. In most children a LGTP is successful, because in time adequate caloric intake can be obtained through the gastric tube. Nevertheless, in 10% of patients a LGTP fails. Some believe that failure could be related to pre-existent delayed gastric emptying. However, this is not based on clinical evidence. An alternative route of enteral feeding is a laparoscopic jejunostomy tube placement (LJTP). A LJTP bypasses the stomach and is therefore hypothesised as a treatment of first choice in children with severe delayed gastric emptying, by some. However, a jejunostomy has major drawbacks. First, after a LJTP, all children are dependent on continues drip feeding, whereas with a LGTP it is possible to administer feedings in portions (bolus). Furthermore, complications as dislocation, obstruction, infection and adhesion ileus are more frequently seen after a LJTP. Gastric emptying studies have never been performed before and after LGTP in children. If a LGTP would lead to a significant increase in gastric emptying, there would be no reason to consider a gastrostomy contraindicated in patients with severe delayed gastric emptying.

Subsequently, jejunostomy tubes need not be placed directly in patients with severe delayed gastric emptying.

Another issue concerning gastrostomy placements is that an increase of gastroesophageal reflux (GER) symptoms after gastrostomy placement is often described in scientific literature. GER is a passive flow of gastric (acidic) contents into the esophagus. However, only a few studies have used objective 24-hour monitoring to evaluate GER after gastrostomy placement. An increase in GER in these studies was not found, which could be explained by the fact that the studied patient population was too limited.Well-designed prospective studies using objective 24-hour pH monitoring in combination with reflux symptom severity scores are lacking.

Study design

Before and 3-4 months after laparoscopic gastrostomy placement the following tests will be performed:

1. 24pH-impedance monitoring;

2. 13C-Octanoic acid breath test;

3. Reflux specific questionnaire: GSQ;

4. HRQoL questionnaire: PedsQL generic score scale 4.0.

Intervention

Laparoscopic gastrostomy placement.

Contacts

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Eligibility criteria

Inclusion criteria

Children (2-18yrs):

1. Referred for LGTP by a pediatrician/pediatric gastroenterologist;

2. Screened by the anaesthesiology department and have no contraindications for surgery;

3. In whom written informed consent can be obtained in:

A. Guardian/parents for all children <18 yrs;

B. Normally developed children >12 yrs.

Exclusion criteria

1. History of gastric surgery;

2. Inability to undergo investigation.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2012
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion

Date:	29-02-2012
Application type:	First submission

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
NTR-new	NL3170
NTR-old	NTR3314
Other	METC UMC Utrecht : 11-029
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A