Clip-assisted duodenal feeding tube placement: a single blind, randomized controlled trial

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To compare migration rate to the stomach or esophagus of clip-assisted endoscopic duodenal feeding tube placement with non clip-assisted endoscopic duodenal tube placement.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON35134

Source
ToetsingOnline

Brief title
CLIP study

Condition

- Other condition
- Gastrointestinal stenosis and obstruction

Synonym
feeding disorder, food passage disorders

Health condition

gastroparese, ernstige reflux, hoog aspiratierisico, proximale enterale fistel, pancreatitis etc

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: Duodenal feeding tube, Endoclip, Migration rate

Outcome measures

Primary outcome

- Migration rate of duodenal feeding tube to the stomach or esophagus

- Failure rate of placement of a duodenual feeding (not in the duodenum,

documented on an abdominal X-ray within three hours of the endoscopic

procedure)

Secondary outcome

1.Succes rate of duodenal feeding tube placement

2. Dwell time of duodenal feeding tube

3. Costs

Study description

Background summary

Duodenal feeding tubes are frequently required for enteral feeding, but have a high migration rate (10-36%). Few clinical studies evaluated the use of clips in anchoring duodenal feeding tubes (DFT) to the duodenal wall. All studies were performed in small, non-randomised, selected groups of patients. By clip-assisted placement of duodenal feeding tubes we hope to prevent migration and decrease the burden for patients and medical costs.

Study objective

To compare migration rate to the stomach or esophagus of clip-assisted endoscopic duodenal feeding tube placement with non clip-assisted endoscopic

duodenal tube placement.

Study design

Single blind randomized controlled trial

Intervention

Patients will be randomised to undergo clip-assisted endoscopic duodenal feeding tube placement (n=72) or *standard* endoscopic duodenal feeding tube placement (n=72)
Thus, the intervention will be the fixation of a duodenal feeding tube by 'clipping' it to the duodenal wall.

Study burden and risks

Burden: One abdominal X-rays is performed to confirm location of duodenal feeding tube in each patient before removal of the duodenal tube. In case of unexpected MRI investigation, in a patient randomised for clip-assisted duodenal feeding tube placement, the duodenal feeding tube (with endoclip attached) has to be removed in advance (by manually withdrawal of duodenal feeding tube, just like in non clip-assisted feeding tube removal). Thirty days after tube feeding, subject will be contacted by phone to answer questions on their experience of tube feeding. This accounts only for subjects admitted to a nursing department, not for subjects admitted to the ICU.
Benefit: We expect that by participating in the study, the risk for tube migration may decrease. However this benefit is not garantueed. This will result in a decrease of symptoms related to migrated feeding tubes and a decrease in repeat upper endoscopies to replace the duodenal feeding tube.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584 CX Utrecht
Nederland
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584 CX Utrecht
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-Subjects (18 years and older) referred for endoscopic duodenal tube placement
-Expected duration of feeding tube in situ at least 3 days
-Written informed consent

Exclusion criteria

-Subjects with a reasonable probalilty of undergoing a MRI investigation
-Known pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-08-2009
Enrollment:	143
Type:	Actual

Medical products/devices used

Generic name:	Resolution endoclip
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	07-07-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	04-06-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	22-09-2010
Application type:	Amendment
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	NL27706.041.09