

# 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.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	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 duodenal feeding (not in the duodenum, documented on an abdominal X-ray within three hours of the endoscopic procedure)

### Secondary outcome

1. Success 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 guaranteed. 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

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## 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 probability 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