Clip-assisted Duodenal Feeding Tube Placement: a Single Blind, Randomized Controlled Trial.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28110

Source
NTR

Brief title
CLIP-study

Health condition

Post-pyloric feeding, Clip-assisted nasoenteral feeding tube, randomised study, migration

Sponsors and support

Primary sponsor: Prof. P.D.Siersema, MD, PhD
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Intervention

Outcome measures

Primary outcome

Number of repeat endoscopies for tube repositioning due to incorrect placed - and migrated tubes.

Secondary outcome

1. Success rate of tube placement (confirmed by abdominal X-ray);

2. Time of endosocpy procedure;

3. Dwell time of feeding tube;

4. Costs;

5. Patient's preferences;

6. Migration rate to stomach or esophagus.

Study description

Background summary

Rationale:

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.

Objective:

To compare the number of repeat endoscopies for migration rate and incorrect placement of endoscopic clip-assisted duodenal feeding tube (C-DFT) placement with non clip-assisted endoscopic duodenal tube placement (DFT).

Study design:

Single blind randomized controlled trial.

Study population:

139 patients (age ≥ 18 years) undergoing placement of duodenal feeding tube for at least 3 days will be enrolled.

Intervention:

Patients will be randomised to undergo clip-assisted endoscopic duodenal feeding tube placement or non clip-assisted endoscopic duodenal feeding tube placement.

Main study parameter:

1. Number of repeat endoscopies for incorrectly
placed and migrated nasoentreal feeding tubes.

Others endpoints:

2. Success rate of tube placment;

3. Time of endoscopic porcedure;

4. Dwell time of feeding tube;

5. Costs;

6. Patient's preferences.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Burden:
An additional abdominal X- ray is performed to confirm location of duodenal feeding tube before removal in each patient. In case of unexpected MRI investigation, in a patient randomised for clip-assisted duodenal feeding tube placement, the DFT with endoclip has to be removed in advance by manual withdrawal.

Benefit:
A decrease can be expected in migration rate, in patients undergoing repeat endoscopic procedures and in cost of medical care.

Study objective

Post-pyloric feeding is frequently required in both critically ill and non-critically ill patients. Duodenal feeding tubes can be placed blind, under fluoscopy or by endoscopy. Migration rates of duodenal tubes are high. By clip-assisted placement of duodenal feeding tubes we hope to prevent migration and decrease the burden for patients and medical costs.

Study design

Daily follow-up untill removal of the tube.

One month after removal of the tube patients will be questioned on their experience of tube feeding. Abdominal X-ray is performed immediatly after tube placement, in case of clinical supicion of migration, and just before removal of the tube.

Intervention

Patients will be randomised to undergo clip-assisted endoscopic duodenal feeding tube placement or non clip-assisted endoscopic duodenal feeding tube placement.

Contacts

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Eligibility criteria

Inclusion criteria

1. All adult patients needing a duodenal feeding tube (including triple lumen tubes);

2. Written informed consent provided by patient or representative;

3. Minimal expected enteral feeding duration of 3 days.

Exclusion criteria

1. Subjects with a reasonable probability of undergoing a MRI scan (Resolution™ endoclips are not MRI compatible);

2. Women with known pregnancy (because of abdominal X-rays performed in order to confirm location of the DFT).

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2009
Enrollment:	140
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-06-2009
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	NL1766
NTR-old	NTR1876
Other	METC UMC Utrecht : 09/146
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A