A randomized trial comparing the Cortrak system with the Endoscopic technique for duodenal feeding tube placement: CORRECT study

No registrations found.

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

Summary

ID

NL-OMON25196

Source
Nationaal Trial Register

Brief title
CORRECT-study

Health condition

All patients with an indication for duodenal feeding tube placement due to delayed gastric emptying at the endoscopy unit or ICU are eligible for this study.

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Success rate of duodenal feeding tube placement; defined as the tip of the tube placed postpyloric and into the duodenum as confirmed by an abdominal X-ray.

Secondary outcome

-Costs associated with duodenal feeding tube placement, calculated by the costs of both procedures and associated complications.

-Time to procedure, defined as time between request for duodenal feeding tube placement and actual start of procedure.

-Time of procedure, defined as time from introduction of endoscope/Cortrak tube in the nose until fixation of the tube to the nose.

-Evaluation endoscopist/nurse, as scored after the procedure on a 11-point Visual Analogue Scale

-Accuracy of tip location with Cortrak, defined as percentage of agreement on tip location between Cortrak system and abdominal X-ray findings. Assessment of the X-ray will be performed by an independent physician not involved in the study. Tip position will be divided in stomach (S), pars superior of the duodenum (D I), pars descendens of the duodenum (D II), pars horizontalis of the duodenum (D III) and pars ascendens of the duodenum (D IV)

-DFT tip location (DI ¨C DIV, jejunum), defined as the location of the tip of the DFT on abdominal X-ray for both endoscopic placement and CORTRAK placement.

-Safety, defined as number of (serious) adverse events related to duodenal feeding tube placement within the first 10 days after placement.

-Use of sedatives

-Reintervention rate within 10 days, total number of reinterventions due to feeding tube migrations and/or feeding tube clogging.

-Patient acceptance (in unsedated patients), as scored by the patient on a 11-point Visual Analogue Scale.

Study description

Background summary

Increasing evidence confirms the important role of enteral feeding in (critically ill) patients. A substantial part of these patients have an indication for duodenal or jejunal feeding. However, duodenal feeding tube (DFT) placement can be difficult, time-consuming, or costly,

depending on the technique used. Endoscopic tube placement has high success rates, but the availability of appropriate staff and specialized equipment is required for this technique, making this technique costly and difficult to provide consistently. Several other techniques for DFT placement have been assessed, all require a high level of expertise and most have not been compared with the endoscopic technique. An electromagnetic tube placement device, the CORTRAK system, is increasing in popularity and several observational studies have demonstrated this technique to be safe, efficient, and cost-effective. Only two small studies have compared the CORTRAK system with other placement techniques in a controlled setting. The aim of this study is to compare the success rate of duodenal feeding tube placement using the CORTRAK system with the endoscopic technique.

Study objective

Duodenal feeding tube placement with the Cortrak system is superior to endoscopic placement with regard to success.

Study design

-Before placement: patient characteristics

-Abdominal X-ray within 3 hours after placement

-Follow-up until 10 days after placement; potential intervention related complications, feeding tube migration or clogging, need for replacement

Intervention

Patients are randomized for electromagnetically visualized duodenal feeding tube placement with the CORTRAK system or duodenal feeding tube placement using endoscopy. The CORTRAK system (CORPAK MedSystems, Inc., Illinois, U.S.A) is a non-invasive electromagnetic tube placement device.

Contacts

Public

P.O. box 85500
University Medical Center Utrecht
Department of Gastroenterology & Hepatology
Room F02.618
W.F.W. Kappelle
Utrecht 3508 GA
The Netherlands
+31 (0)88 5750724

Scientific

P.O. box 85500
University Medical Center Utrecht
Department of Gastroenterology & Hepatology
Room F02.618
W.F.W. Kappelle
Utrecht 3508 GA
The Netherlands
+31 (0)88 5750724

Eligibility criteria

Inclusion criteria

-All patients needing a duodenal feeding tube

-Written informed consent provided by patient or representative

-¡Ý18 years

Exclusion criteria

-Implantable pacing devices (potential interference with the signal transmission)

-Altered anatomy of the upper gastrointestinal tract due to surgery of the esophagus, stomach or duodenum

-High suspicion of stenosis or obstruction in the upper digestive tract

-Esophageal varices

- Signs of active upper gastrointestinal bleeding.

-Woman with known pregnancy (because of abdominal X-rays performed in order to confirm location of the duodenal feeding tube)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-12-2013
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion

Date:	29-10-2013
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	NL4142

Register	ID
NTR-old	NTR4286
Other	Ethical committee Utrecht : 12-629

Study results

Summary results
N/A