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

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

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON25196

**Bron**
Nationaal Trial Register

**Verkorte titel**
CORRECT-study

**Aandoening**

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.

### Ondersteuning

**Primaire sponsor:** University Medical Center Utrecht
**Overige ondersteuning:** Medicor

### Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

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.

# Toelichting onderzoek

### Achtergrond van het onderzoek

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.

### Doel van het onderzoek

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

### Onderzoeksopzet

-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

### Onderzoeksproduct en/of interventie

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.

# Contactpersonen

## Publiek

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## Wetenschappelijk

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

-All patients needing a duodenal feeding tube

-Written informed consent provided by patient or representative

-¡Ý18 years

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

-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)

## Onderzoeksopzet

### Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Open / niet geblindeerd |
| Controle: | Actieve controle groep |

### Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestart |
| (Verwachte) startdatum: | 05-12-2013 |
| Aantal proefpersonen: | 200 |
| Type: | Verwachte startdatum |

## Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 29-10-2013 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL4142 |
| NTR-old | NTR4286 |
| Ander register | Ethical committee Utrecht : 12-629 |

# Resultaten

**Samenvatting resultaten**
N/A