NUTritional Route In Esophageal resectioN Trial II

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The aim of this study is to investigate the effects of early start versus delayed start of oral intake on postoperative recovery and pulmonary complications following esophagectomy. This is a non-inferiority trial.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON42802

Source
ToetsingOnline

Brief title
NUTRIENT II

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
esophagectomy

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Eigen geld maatschap Catharina Ziekenhuis Eindhoven

Intervention

Keyword: delayed oral intake, early oral intake, esophagectomy, nutrition

Outcome measures

Primary outcome

- Functional recovery

Secondary outcome

- Pulmonary complications (Pneumonia, Acute respiratory distress syndrome

(ARDS), respiratory insufficiency requiring treatment)

- Anastomotic leakage (clinically and amylase levels in drain fluid)

- Nutritional status (weight loss, sarcopenia, intake)

- Need for parenteral feeding/ placement of a nasojejunal feeding tube

- Need for additional surgical, radiological or endoscopic interventions

- 30-day surgical complications (classified according to Clavien-Dindo)

- Other complications requiring treatment (i.e. urinary tract infection)

- Need for ICU admission and total length of ICU stay

- Quality of life

Study description

Background summary

Early oral feeding is safe and beneficial in most types of gastro-intestinal surgery and is a crucial part of fast track or enhanced recovery protocols. Following esophagectomy, fast track programs are increasingly being applied, resulting in a reduced length of stay, perioperative morbidity and hospital charges. However, the feasibility and safety of oral intake directly following esophagectomy remains unclear.

Mostly, a nil-by-mouth regimen is applied during the first postoperative week,

to reduce the incidence and severity of postoperative pneumonia and anastomotic leakage. Since early enteral nutrition following esophagectomy is considered to be beneficial a nasojejunal tube or jejunostomy tube is placed to bypass the oral route. In this way, patients are subjected to the discomfort and complications of a nasojejunal tube or jejunostomy tube, potentially hampering their recovery.
Two retrospective studies investigated a further delay of the initiation of oral nutrition, even up to four weeks following esophagectomy. Both studies found a significant reduction in anastomotic leakage with an extended delay of oral nutrition following esophagectomy compared to a conventional 5-7 days nil by mouth regimen. However, these studies were at risk for bias and extrapolation of these results to the clinical situation may not be valid.

On the other hand, early initiation of oral nutrition has been shown to be feasible in many types of gastrointestinal surgery, including upper gastrointestinal surgery. Furthermore, in a previous feasibility study (Nutrient I trial) has been shown that direct oral intake following esophagectomy was feasible and did not result in an increase of major complications. An important argument to delay oral intake is the risk of (aspiration) pneumonia. The feasibility trial showed that pulmonary complications were not significantly different in patients that were fed orally directly, when compared with a historical cohort in which oral intake was delayed. Interestingly, direct oral intake even resulted in less postoperative pulmonary complications.
It remains unclear what the best strategy is for nutrition in the early postoperative phase following esophagectomy.

Study objective

The aim of this study is to investigate the effects of early start versus delayed start of oral intake on postoperative recovery and pulmonary complications following esophagectomy. This is a non-inferiority trial.

Study design

A prospective randomized controlled trial (RCT) performed at the Catharina Hospital Eindhoven and the Hospital Group Twente.

Intervention

Early oral feeding after an esophagectomy. Patients will start a liquid oral diet directly postoperatively.

Study burden and risks

Patients will recieve either oral feeding or enteral feeding, during the

firstfive days postoperatively. Both feedings routes are without extra risks for the patient. The extent of the burden is not different from normal standard care during the postoperative period.

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

• Patients that undergo a minimally invasive/hybrid esophagectomy with intrathoracic anastomosis for cancer.
• written informed consent
• age >18 years

Exclusion criteria

• Inability for oral intake
• Inability to place a surgical feeding jejunostomy
• Inability to provide written consent or inability to fill out questionnaires
• Swallowing disorder
• Achalasia
• Malnutrition (defined as >15% weight loss just before start of the surgery)
• Karnofsky Performance Status < 80

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2015
Enrollment:	148
Type:	Actual

Ethics review

Approved WMO

Date:	01-09-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	15-01-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	09-12-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 21339
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
ClinicalTrials.gov	NCT02378948
CCMO	NL52591.060.15
OMON	NL-OMON21339