Nutritional Route In Esophageal Resection trial

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This study aims to determine whether early start of oral intake in patients that underwent an esophagectomy is feasible and safe.

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

Summary

ID

NL-OMON39631

Source
ToetsingOnline

Brief title
NUTRIENT

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal therapeutic procedures

Synonym
esophagectomy

Research involving
Human

Sponsors and support

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

Intervention

Keyword: early oral intake, esophagectomy, nutrition

Outcome measures

Primary outcome

The effect of an early oral intake regimen on the percentage and severity (according to the modified Clavien Dindo classification for surgical complications) of anastomotic leakage and pneumonia.

Secondary outcome

• Daily caloric intake during the postoperative admission

• Need and amount of artifical nutrition (parenteral feeding/ naso-jejunal tube feeding)

• Occurrence of vomiting

• Placement of a nasogastric tube

• Length of hospital stay

• Hospital re-admissions within 30 days of discharge

• Complications classified according to the Clavien-Dindo classification

• Need for ICU admission and total length of ICU stay

• Complications of a jejunostomie

• total caloric and protein intake postoperative day 5

Study description

Background summary

In the past decade, fast-track programs such as the enhanced recovery after surgery (ERAS) program have changed the view on postoperative nutrition in

abdominal surgery. Many studies, especially in colorectal surgery, have shown that there is no clear advantage to withhold enteral nutrition in the direct postoperative phase. Early feeding may even be beneficial compared with the traditionally applied nil-by-mouth strategy. Early start of postoperative enteral nutrition has also been shown safe in other forms of abdominal surgery such as in gynaecologic surgery.

However, for patients undergoing an esophagectomy it is unclear what the best route of feeding is. There is a concern that early oral intake would result in vomiting with subsequent aspiration pneumonia. Furthermore the sequelae of anastomotic leakage are thought to be more severe if the leaked fluids contain food besides to saliva. Although these arguments are generally applied, there is no clear supporting scientific evidence. Interestingly, these arguments were similarly used in colorectal surgery to support the nil-by-mouth regimen for many years before introduction of fast-track protocols.

There is only one retrospective study that suggests anastomotic leak rates are lower when a radiographic contrast swallow was omitted postoperatively and patients are fed over a jejunostomy and kept nil-by-mouth for 4 weeks. However, these data are difficult to interpret since it is unclear if their findings result from a difference in anastomotic leak definitions between both groups, timing of first enteral intake, timing of oral intake, or other, unknown factors.

On the other hand some studies show that early oral intake is feasible and can result in faster recovery of bowel function and a shorter hospitalization in partial or total gastrectomy. Furthermore, it has been shown that early oral intake directly after major upper abdominal surgery, including esophagectomy, does not increase morbidity compared with traditional care consisting of postoperative fasting. However, only few patients undergoing esophagectomy were included in this trial. Finally, experimental evidence shows that early enteral feeding above the anastomosis improves anastomotic healing after upper abdominal surgery in rats.

Therefore, we questioned whether or not it is justified to delay the start of oral intake after esophagectomy. Before a comparative study can be performed it should be determined whether or not it is feasible to start oral intake early after esophagectomy.

Study objective

This study aims to determine whether early start of oral intake in patients that underwent an esophagectomy is feasible and safe.

Study design

The NUTRIENT trial is a single-arm multicentre feasibility trial. All patients will follow a standardised clinical pathway in which oral intake is allowed directly after surgery.

Intervention

direct oral feeding

Study burden and risks

The study group has performed a amongst Dutch Upper gastrointestinal surgeons and this survey shows that some clinics stimulate early oral intake and others advocate stimulated a delayed oral intake. Early oral feeding is traditionally postponed in order to decrease the risk of aspiration pneumonia and prevent harmful effects of oral intake in case of anastomotic leakage. Although this has never been substantiated and clinical evidence is lacking, this is a potential hazard for the patient. On the other hand, delayed oral intake necessitates a feeding jejuonostomy which is also accompanied with complications. This also is a potential risk for the patient besides the discomfort to be kept nil by mouth for 7 days. For safety an independent Data Safety Monitoring Board will monitor the study and evaluate potential safety issues.

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

- age > 18 years
- Written informed consent
- Indication for esophagectomy
- intrathoracic anastomosis

Exclusion criteria

- Inability for oral intake
- Mental retardation
- Swallowing disorder
- weight loss of >15% at start of surgery

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	04-09-2013
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	05-08-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	02-12-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-03-2014
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: 22161
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL39949.060.12
OMON	NL-OMON22161