NUTritional Route In Esophageal resectioN Trial.

No registrations found.

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

Summary

ID

NL-OMON22161

Source
Nationaal Trial Register

Brief title
The NUTRIENT trial

Health condition

esophagectomy (slokdarm resectie)
nutrition (voeding)
early oral intake (vroege orale voeding)

Sponsors and support

Primary sponsor: Catharina Hospital Eindhoven

Intervention

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 artificial nutrition (naso-jejunal tube feeding / parenteral nutrition)

- 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

Study description

Background summary

The Nutrient Trial is a single arm feasibility trial investigating early oral intake after esophagectomy. Primarily the impact on anastomotic leakage and pneumonia rate and severitiy will be carefully monitored.

Study objective

Early oral intake after esophagectomy is feasible and safe.

Study design

All primairy and secondary outcome measures are measured at the moment of discharge except for 2.

1. The caloric intake is measured on day 5 postoperative.

2. The hospital readmissions are determined within 30 days of discharge.

Intervention

- De intervention consists of an oral intake scheme that is started from postoperative day one, under supervision of a dietician. Previously patients undergoing esophagectomy were

kept nill-by-mouth untill day 5-7 postoperative, however, in this trial we will investigate if it is feasible and safe to start oral intake early after esophagectomy. In other wordt: patients will start a liquid diet from postoperative day 1, while previously they were not allowed to eat untill day 5-7 after the operation.

- There is no control group, for this is a single arm descriptive phase 2 trial.

- Duration of the intervention is not applicable to this study, because it consists of early oral intake. It is the timepoint that the oral intake is started that is relevant here.

Contacts

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Eligibility criteria

Inclusion criteria

age > 18 years

written informed consent

indication for esophagectomy

Exclusion criteria

inablitity for oral intake

mental retardation

swallowing disorder

weight loss of >15% at start of surgery

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-08-2013
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion

Date:	22-08-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39631
Bron: ToetsingOnline

Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3851
NTR-old	NTR4136
CCMO	NL39949.060.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39631

Study results

Summary results
N/A