Kan betere voeding gewichts- en spierverlies bij patiënten die een slokdarmoperatie ondergaan tegengaan?

No registrations found.

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

Summary

ID

NL-OMON25924

Source
NTR

Brief title
SPOT-trial

Health condition

Esophageal cancer patients undergoing an esophagectomy

Sponsors and support

Primary sponsor: University Medical Center Groningen
Secundary
Gelre Hospital Apeldoorn
Source(s) of monetary or material Support: Still pending: UMCG

Intervention

Outcome measures

Primary outcome

Sarcopenia (muscle loss) measured by psoas muscle index by a CT-scan

Secondary outcome

• Loss of muscle mass, measured by handgrip strength; arm circumference & triceps skinfold thickness; creatinin & urea in 24-hour urine.

• Incidence of Clavien Dindo complications

• Length of hospital stay and re-admittance rate

• Survival

• Quality of Life

Study description

Background summary

In one Dutch hospital cancer patients undergoing esophagectomy will receive a goal directed nutritional support; in another Dutch hospital care as usual will be provided.

Study objective

A goal directed nutritional support can reduce sarcopenia in surgical esophagus patients.

Study design

At baseline, one-year after surgery for the primary outcomes. Other measurements will also be performed before surgery, and 3 and 6 months after surgery.

Intervention

Strict nutrtional protocol consisting of:

• One dietitian: case manager during all stages of treatment

• Use PG-SGA-questionnaire before consult

• Weekly registration of nutritional intake

• Energy needs measured by indirect colorimetry

• Proactive nutritional support

Contacts

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Eligibility criteria

Inclusion criteria

• Patients that undergo a (minimally invasive or hybrid: laparoscopy and thoracotomy or conventional open surgery) esophagectomy for cancer with cervical or intrathoracic anastomosis

• Written informed consent

• Age > 18 years

• Histologically confirmed, previously untreated esophageal cancer

• Considered suitable for radical surgery with curative intent.

• Squamous cell carcinoma, adenocarcinoma, and undifferentiated carcinoma are included.

• Tumor location included the upper, middle, lower thirds of the esophagus and esophagogastric junction tumors, but excluded postcricoid cancers.

Exclusion criteria

• Salvage esophagectomy; after previous histologically confirmed esophageal cancer treated by ‘definitive’ radio- or radiochemotherapy

• Inability to provide written consent or inability to fill out questionnaires

• Previous or concomitant malignant disease, apart from basal-cell carcinoma

• Cervical lymph-node involvement or evidence of metastases.

• Karnofsky Performance Status < 80

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2017
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-01-2017
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	NL6179
NTR-old	NTR6326
CCMO	NL57787.042.16

Study results