Can goal directed nutritional support reduce sarcopenia in surgical oesophagus patients?

Published: 03-01-2019
Last updated: 14-12-2024

This study investigates the impact of a goal directed nutritional support protocol on sarcopenia in oncological patients undergoing an esophagectomy and secondary the incidence of anastomotic leakage and pneumonia, surgical infection and lenght of...

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

Summary

ID

NL-OMON46171

Source
ToetsingOnline

Brief title
Sarcopenia Prevention in Oesophagectomy Trial (SPOT)

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
Oesophagectomy and muscle loss

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Baxter,deels van eigen afdeling

Intervention

Keyword: Cancer, Oesophagectomy, Sarcopenia, Survival

Outcome measures

Primary outcome

Sarcopenia (psoas and muscle area on L3 level) is the primary outcome. The

dofference in skeletal muscle index between the baseline CT-scan and the

routine CT-scan made before surgery will be the primary outcome

Secondary outcome

Secondary outcomes are anastomic leakage, pneumonia, infection, length of

hospital stay, readmission rate, survival

Study description

Background summary

Overall survival of patients with resectable esophageal cancer remains poor, with 1 5-year survival of 23-47%. At time of diagnosis 50-85% of patients with esophageal cancer are malnourished. This study investigates whether a goal directed nutritional support protocol in oncological patients undergoing an esophagectomy can reduce sarcopenia (muscle loss) and complications in these patients.

Study objective

This study investigates the impact of a goal directed nutritional support protocol on sarcopenia in oncological patients undergoing an esophagectomy and secondary the incidence of anastomotic leakage and pneumonia, surgical infection and lenght of stay, radmission rate and survival.

Study design

In this before/after multicenter study results of a goal directed nutritional support wil be compared with nutritional care as usual. In het UMCG, 50 patients who had surgery in the past year, will be asked to take an additional CT-scan one year after surgery. In the UMCG 50 patients will recieve the

intervention. In the ZGT hospital, first, 50 patients will be included with care as usual. Next, 50 patients will recieve the intervention as well.

Intervention

The intervention is of a goal directed nutritional support, which consists of:
-The use of one nutritional case manager: one dietitian during the whole treatment: during radiochemotherapy, hospitalizationa and postoperatively
-Monitoring of nutritional assessment oby PG-SGA (more awareness of malnutrition)
-Weekly registration of food intake
-Measuring of energy-requirements by an indirect calorimeter (results in better energy requirements than use of calculation formulas)
-Proactive use of sip-feedings, enteral tube feeding and parenteral nutrition during the whole treatment period

Study burden and risks

Following the regular visits to the hospital, the patient will vist a nurse or dietitian seven times in 15 months. A visit takes about 30 to 60 minutes extra.
The following additional procedures will take place:
-Measurement of the upper arm and hand grip strength
-Combined with ususal blood tests an additional blood sample taken to study the nutritional status.
-The patient will be asked 3x to collect 24-hours urine to determine the muscle mass
The patient is given a nutritional support from a dietitian
The patient will be asked to fill out two short questionnaires for each clinic visit (five times). These questionnaire concern their (problems with) food intake and their quality of life
-Daily energy requirements will be detemined twice at rest (of which 1x during hospitalization). For this purpose, the amount of oxygen and carbion dioxide is measured in the inhaled and exhaled air for 15 mintues while the patient is lying on a bed. Meanwhile, by means of four patched on the patient's hand and foot the muscle, fat and water content of the body will be determined (bio-impedance analyses)
-The patient will be asked to wat a pedometer every two days before their visit to the surgeon
-The patient receives an additional CT-scan wit a lower radiation dose. The CT-scan will onlu be used to determine the muscle mass. It is not used for any other (diagnostical) purpose.
-The small additional radiation exposure of the additional low dose CT-scan and the extra time the research will take are neglible. This will not outweigh the benefits of the potential increase of well-being and possibly better nutritional status and longer survival of these patients. Most people are very interested in their bodycomposition.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients >18 years that undergo an esophagectomy for cancer with cervial or intrathoracic anastomosis.
Written informed consent

Exclusion criteria

Inability to provide written consent or inability to fill out questionnaires

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	24-01-2019
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	03-01-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL66893.042.18
Other	UMCG201600361