Preoperative training for patients with esophageal cancer who will undergo resection.

No registrations found.

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

Summary

ID

NL-OMON22015

Source
Nationaal Trial Register

Brief title
PC-OCR

Health condition

esophaguscardiaresection
esophageal cancer
cancer of the esophagus
oesophaguscardiaresectie
oesophaguscardiacarcinoom
slokdarmkanker

Sponsors and support

Primary sponsor: M. Sosef
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

1. Scores on QoL and anxiety and depression questionnaires;

2. Lungfunctiontests;

3. (Inspiratory) muscle force measurements;

4. BMI;

5. MUST-score;

6. Nutritional status.

Secondary outcome

1. Complications;

2. Morbidity;

3. Days on ICU;

4. Hospital length of stay;

5. Re-admission and mortality.

Study description

Background summary

Background of the study:

The incidence of esophageal cancer has strongly increased the last 15 year, from 5.4 to 9.5 per 100.000. The 5-year survival rate after curative therapy seems to increase slowly from ±15% to ±35%.
Because of agreements in the region, the esophaguscardiaresections (OCR) of Southern Limburg are situated at AtriumMC, Heerlen. On yearly basis an amount of 40-45 patients is expected.

Objective of the study:

The purpose of this research is to investigate the effect of multimodal preconditioning for patients who will undergo esophaguscardiaresection.

Study design:

This will be a prospective pilot study where 10 patients will follow the preconditioning protocol compared to 10 patients who will receive the usual care during the period between neoadjuvant therapy and surgery.

Study population:

Patients with esophaguscardia cancer who will be indicated for esophaguscardiaresection during the meeting of oncology. This implicates both the adeno- or squamouscellcarcinoma.

Intervention (if applicable):

Nutrition: weekly consults consisting of nutritional assessment, MUST score, energy and protein intake and BMI. If there is (a risk of) malnutrition, the patient will get an individualized nutrition plan, consisting not only of advice, but also strict nutritional support. During the treatment the objective is nutrition consisting of sufficient protein and energy values according to the CBO guidelines of perioperative nourishment.

Physiotherapy: daily physiotherapy for 15 minutes with an inspiratory threshold device. A supervised physiotherapy with walking, cycling and muscle training two times a week two hours in the AtriumMC. A single referral to the smoking cessation outpatient department when necessary. Check up with twice a long function investigation and mouth pressure measurement, weekly inspiratory muscle force measurements.

Psychology: Proceeding chemo and/or radiotherapy patients will visit the psycologist. After neoadjuvant therapy they will get a prolonged intake where questionnaires regarding complaints, quality of life, anxiety and depression will be filled out. On a daily basis patients will perform visualization exercises with the use of a relaxation therapy CD. When necessary, patients will receive a consult every two weeks.

Primary study parameters/outcome of the study:

Scores on the questionnaires, long function, (inspiratory) muscle force measurements, mound pressure measurements, BMI, force in the hand.

Secundary study parameters/outcome of the study (if applicable):

Complications, hospital length of stay, re-admission and mortality.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness (if applicable):

This research is moderately aggravating for patients. Time investment needs to be made and it might take some physical effort. There are no known risks for this research.

Study objective

Does preconditioning prior to an esophaguscardiaresection result in enhanced mental state, cardiopulmonairy condition and nutritional status.

Study design

1. At time of diagnosis;

2. After neoadjuvant therapy;

3. Before operation.

Intervention

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Contacts

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Eligibility criteria

Inclusion criteria

Patients (>18 year) with esophageal cancer who will undergo esophaguscardiaresction after neoadjuvant therapy.

Exclusion criteria

Lack of informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-06-2009
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-06-2009
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	NL1742

Register	ID
NTR-old	NTR1852
Other	: 08T79
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
none