Preonditioning for patients who will undergo esophaguscardiaresection

Published: 18-02-2009
Last updated: 06-05-2024

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

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

Summary

ID

NL-OMON33604

Source
ToetsingOnline

Brief title
PC-OCR studie

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified

Synonym
cancer of the esophagus, esophageal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Atrium Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cancer of the esophagus, esophageal cancer, esophaguscardiaresection, preconditioning

Outcome measures

Primary outcome

Scores on the questionnaires, long function, muscle force measurements, BMI,

handdynamometry.

Secondary outcome

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

Study description

Background summary

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, curative esophaguscardiaresections (OCR) of Southern Limburg are situated at AtriumMC, Heerlen. On yearly basis an amount of 40-45 patients is expected.

Study objective

The purpose of this research is to investigate the effect and feasability 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.

Intervention

Nutrition: Weekly consults consisting of nutritional assessment, MUST score,

measurement of 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. 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 muscle force measurements.
Psychology: Before chemo and/or radiotherapy starts, 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.

Study burden and risks

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.

Contacts

Public
Atrium Medisch Centrum

henri dunantstraat 5
6401 CX Heerlen
Nederland
Scientific
Atrium Medisch Centrum

henri dunantstraat 5
6401 CX Heerlen
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

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:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-10-2009
Enrollment:	20

Type:	Actual

Ethics review

Approved WMO Date:	18-02-2009
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL25857.096.08