

# Preconditioning in patients undergoing esophaguscardiaresection.

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|                              |  |
|------------------------------|--|
| <b>Ethical review</b>        | Approved WMO   |
| <b>Status</b>                | Recruitment stopped                                      |
| <b>Health condition type</b> | Malignant and unspecified neoplasms gastrointestinal NEC |
| <b>Study type</b>            | Interventional   |

## Summary

### ID

NL-OMON35645

### Source

ToetsingOnline

### Brief title

PC-OCR-II study

### Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

### Synonym

esophageal carcinoma, esophagus 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:** esophageal carcinoma, esophaguscardiaresection, preconditioning, pre-operative

## Outcome measures

### Primary outcome

- \* Cardiorespiratory fitness: consisting of VO2 max measurement, spirometry  
lungfunction and mouthpressure
- \* Nutritional status
  - o BMI
  - o Weight
  - o Muscleforce of the hand, triceps and quadriceps
  - o MUST score
  - o Nutritional Risk Index and Instant Nutritional Assesment
- \* Quality of Life measured with the EORTC QLQ-C30 and OES18 questionnaires

### Secondary outcome

- \* Postoperative complications
- \* Length of hospital stay
- \* Length of stay on intensive care unit
- \* Mortality
- \* Re-admission

## 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  $\pm 15\%$  to  $\pm 35\%$ . The curative treatment of esophageal cancer consists of radical resection (esophagus cardia resection, OCR), preceded by neoadjuvant chemoradiation. Esophagus cardia resections are seen as low-volume, high-risk surgery. Cardiorespiratory fitness, muscleforce, nutritional status and quality of life are threatened in patients with esophageal carcinoma. Especially these aspects have an assumed negative effect on postoperative outcome measures like length of hospital stay, morbidity and mortality. It has recently been demonstrated that some of those aspects can generally be improved preoperative. This resulted in improvement of the postoperative outcome measurements.

## **Study objective**

The purpose of this research is to investigate the effect of early multimodal preconditioning for patients who will undergo esophaguscardiaresection will lead to improvement of cardiorespiratory fitness, nutritional status and quality of life. This could come with improvement of postoperative morbidity and mortality.

## **Study design**

This will be a RCT study where 38 patients will follow the preconditioning protocol compared to 38 patients who will receive the usual current care during the period from shortly after the diagnosis untill surgery.

## **Intervention**

The interventiongroup will receive the next interventions:

Nutrition:

Two 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 of not only 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.

Physical therapy:

Daily physical therapy for 15 minutes with an inspiratory threshold device at home. Supervised physical therapy two times a week for two hours preferably in the Atrium MC Heerlen. This physical therapy consists of training on the treadmill, hometrainer. Specific musclegroups will be trained with weights. This all to improve the patient's cardiorespiratory fitness.

The interventiongroup as well as the controllgroup will be subject to measurements three times during the preconditioning path. This will be done before and after neoadjuvant therapy and shortly before surgery.

The lungfunction department will be involved by taking the spirometry tests including the mouthpressure. They will also do the VO2 max test. The physical therapist will measure weight, muscleforce of the hand, triceps and quadriceps using a grip strength dynamometer and microFET. Bloodsamples will be taken three times during the path. Additionally patients will have to fill in Quality of Life questionnaires and the MUST score (malnutrition) will be determined. Quality of Life will be determined also four weeks postoperative.

### **Study burden and risks**

This research is aggravating for patients. Time investment needs to be made and it will take physical effort, depending on the group. Measurement of the VO2 max will be the most intensive test for patients. The Atrium MC has a centerfunction for Limburg, but not all patients live nearby. The traveldistance will cause extra effort for those living far from the Atrium MC. There are no known risks for this research, except for infection and bleeding after bloodsampling.

## **Contacts**

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## **Trial sites**

### **Listed location countries**

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Patients (> age 18) with esophageal, who will have resection after neoadjuvant therapy.

### Exclusion criteria

Absence of a signed informed consent.

## Study design

### Design

|                     |                             |
|---------------------|-----------------------------|
| Study type:         | Interventional              |
| Intervention model: | Parallel                    |
| Allocation:         | Randomized controlled trial |
| Masking:            | Open (masking not used)     |

**Primary purpose:** Treatment

### Recruitment

|                           |                     |
|---------------------------|---------------------|
| NL                        |                     |
| Recruitment status:       | Recruitment stopped |
| Start date (anticipated): | 01-02-2012          |
| Enrollment:               | 76                  |
| Type:                     | Actual              |

## Ethics review

Approved WMO

Date: 16-12-2011

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     | NL38167.096.11 |