

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

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

|                             |                       |
|-----------------------------|-----------------------|
| <b>Ethische beoordeling</b> | Positief advies       |
| <b>Status</b>               | Werving gestart       |
| <b>Type aandoening</b>      | -                     |
| <b>Onderzoekstype</b>       | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON22015

### Bron

NTR

### Verkorte titel

PC-OCR

### Aandoening

esophaguscardiaresection  
esophageal cancer  
cancer of the esophagus  
oesophaguscardiaresectie  
oesophaguscardiacarcinoom  
slokdarmkanker

### Ondersteuning

**Primaire sponsor:** M. Sosef

**Overige ondersteuning:** none

### Onderzoeksproduct en/of interventie

# Uitkomstmaten

## Primaire uitkomstmaten

1. Scores on QoL and anxiety and depression questionnaires;<br>
2. Lungfunctiontests;<br>
3. (Inspiratory) muscle force measurements;<br>
4. BMI;<br>
5. MUST-score;<br>
6. Nutritional status.

## Toelichting onderzoek

### Achtergrond van het onderzoek

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  $\pm 15\%$  to  $\pm 35\%$ .

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 psychologist. 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.

#### Secondary 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.

#### **Doel van het onderzoek**

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

### **Onderzoeksopzet**

1. At time of diagnosis;
2. After neoadjuvant therapy;
3. Before operation.

### **Onderzoeksproduct en/of interventie**

#### 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:

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Proceeding chemo and/or radiotherapy patients will visit the psychologist. 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.

## **Contactpersonen**

### **Publiek**

Atrium MC Heerlen  
Chirurgie  
M. Sosef

Postbus 4446  
Heerlen 6401 CX  
The Netherlands  
+31 45 576 66 66

## Wetenschappelijk

Atrium MC Heerlen  
Chirurgie  
M. Sosef  
Postbus 4446  
Heerlen 6401 CX  
The Netherlands  
+31 45 576 66 66

## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Lack of informed consent.

## Onderzoeksopzet

### Opzet

|                  |                         |
|------------------|-------------------------|
| Type:            | Interventie onderzoek   |
| Onderzoeksmodel: | Parallel                |
| Toewijzing:      | N.v.t. / één studie arm |
| Blinding:        | Open / niet geblindeerd |
| Controle:        | Geneesmiddel            |

## Deelname

|                         |                      |
|-------------------------|----------------------|
| Nederland               |                      |
| Status:                 | Werving gestart      |
| (Verwachte) startdatum: | 11-06-2009           |
| Aantal proefpersonen:   | 20                   |
| Type:                   | Verwachte startdatum |

## Ethische beoordeling

|                 |                  |
|-----------------|------------------|
| Positief advies |                  |
| Datum:          | 11-06-2009       |
| Soort:          | Eerste indiening |

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

| Register       | ID                                  |
|----------------|-------------------------------------|
| NTR-new        | NL1742                              |
| NTR-old        | NTR1852                             |
| Ander register | : 08T79                             |
| ISRCTN         | ISRCTN wordt niet meer aangevraagd. |

## Resultaten

### Samenvatting resultaten

none