

# Node study: 'Esophageal resection for patients with esophageal cancer and cervical lymph node metastases'

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To assess the safety and feasibility of curative esophagectomy combined with three field lymphadenectomy after chemo-radiation in Western patients with resectable thoracic esophageal carcinoma and cervical lymph node metastases in level III and/ or...

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

## Summary

### ID

NL-OMON44167

### Source

ToetsingOnline

### Brief title

Node study

### Condition

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

### Synonym

esophageal cancer with cervical lymphnode metastasis

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Heelkunde, chirurgie

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** cancer, cervical metastasis, Esophagectomy, three-field lymphadenectomy

## Outcome measures

### Primary outcome

Primary outcome is the percentage of overall postoperative complications grade 3b and higher as stated by the modified Clavien-Dindo classification (MCDIC).

### Secondary outcome

Secondary outcomes are individual components of the primary outcome, complications grade 2 and 3a, mortality, operation related events and postoperative recovery including quality of life, disease free survival, 5 year overall survival and if applicable location of recurrent disease.

## Study description

### Background summary

There is no world wide consensus on the oncological benefit versus increased morbidity associated with three field lymphadenectomy in patients with esophageal cancer and cervical lymph node metastases. In Asian countries, esophagectomy is commonly combined with a three field lymphadenectomy, including resection of cervical, thoracic and abdominal lymph nodes. However, in Western countries patients with cervical lymph node metastases are generally precluded from curative treatment.

### Study objective

To assess the safety and feasibility of curative esophagectomy combined with three field lymphadenectomy after chemo-radiation in Western patients with resectable thoracic esophageal carcinoma and cervical lymph node metastases in level III and/ or IV of the neck. Secondary objective is to determine the effect on survival and recurrence.

## Study design

Mono centre prospective fase II single-arm feasibility trial.

## Intervention

Transthoracic esophageal resection combined with three field lymphadenectomy.

## Study burden and risks

The additional burden for the patient consists of an esophagectomy combined with three field lymph node dissection including thoracic, abdominal, and bilateral cervical level III, and IV lymph node dissection. Pre-operative evaluation will be performed according to general practice. Postoperative care and outpatient visits do not differ from regular protocol. The study is associated with a moderate risk classification. As there is a potential survival benefit, we consider the additional burden and risks justified. This study is designed as a one group study, which eliminates group relatedness.

## Contacts

### Public

Selecteer

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### Scientific

Selecteer

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- Histologically proven squamous cell carcinoma or adenocarcinoma or undifferentiated carcinoma of the intrathoracic esophagus.
- Surgical resectable carcinoma (T1-4a, N1-3)
- Histologically/ cytologically proven resectable cervical lymph node metastases level III and/ or IV
- Age  $\geq 18$
- European Clinical Oncology Group (ECOG) performance status 0,1 or 2
- Written informed consent

### Exclusion criteria

- Distant metastases
- Esophageal carcinoma  $< 3$  cm beneath UES
- Carcinoma of the gastro-esophageal junction (GEJ) with major tumor in the gastric cardia (Siewert III)
- Former radiotherapy or chemotherapy for esophageal carcinoma
- Former radiotherapy precluding radiotherapy according the CROSS protocol
- Inadequate pulmonary function disabling transthoracic resection
- Previous neck dissection
- New York heart association class III/IV and no history of active angina. Patients with a history of significant ventricular arrhythmia requiring medication or congestive heart failure. History of 2nd or 3rd degree heart blocks

## Study design

### Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose: Treatment

## Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 11-02-2015

Enrollment: 20

Type: Actual

## Ethics review

Approved WMO

Date: 21-01-2015

Application type: First submission

Review commission: METC NedMec

Approved WMO

Date: 27-05-2015

Application type: Amendment

Review commission: METC NedMec

Approved WMO

Date: 15-01-2016

Application type: Amendment

Review commission: METC NedMec

Approved WMO

Date: 23-11-2016

Application type: Amendment

Review commission: METC NedMec

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

ID: 24304

Source: NTR

Title:

## In other registers

Register	ID
ClinicalTrials.gov	NCT02426879
CCMO	NL48231.041.14
OMON	NL-OMON24304

## Study results

Results posted: 16-02-2023

### First publication

10-12-2022