Esophagectomy for patients with resectable esophageal cancer and cervical lymph node metastases

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24304

Source
Nationaal Trial Register

Brief title
EPIC

Health condition

Esophageal cancer; Cervical lymph node metastasis

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: initiator

Intervention

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 (MCDC).

Secondary outcome

Secondary outcomes are mortality, operation related events and postoperative recovery, disease free survival, overall survival and if applicable the location of recurrent disease.

Study description

Background summary

Rationale: 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.

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.
Secondary objective is to determine the effect on survival and recurrence.

Study design: Mono centre prospective single-arm feasibility trial.

Study population: Western patients diagnosed with resectable (cT1-4a, N0-3) intra thoracic esophageal carcinoma with histological or cytological proven cervical lymph node metastases.

Intervention: Transthoracic esophageal resection combined with three field lymphadenectomy.

Main study parameters/ endpoints: Primary outcome is the percentage of overall complications grade 3b and higher as stated by the Modified Clavien-Dindo classification. Secondary outcomes are mortality, operation related events and postoperative recovery, disease free survival, overall survival and if applicable the location of recurrent disease.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The additional burden for the patient consists of an esophagectomy combined with three field lymph node dissection including thoracic, abdominal, and bilateral cervial level II, II, and IV (parajugular and posterior triangle) 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 high 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.

Study objective

Transthoracic esophageal resection combined with three field lymphadenectomy for patients with esophageal cancer and proven cervical lymph node metastasis is feasible and safe and might result in better survival rates.

Study design

- Peri-operative

- Post-operative during hospital admission

- During follow up period of 5 years. (fist year post surgery every 3 months, second year every 6 months, third, fourth and fifth year once every year)

Intervention

Transthoracic esophageal resection combined with three field lymphadenectomy.

Contacts

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Eligibility criteria

Inclusion criteria

-Histologically proven squamous cell carcinoma, adenocarcinoma or undifferentiated carcinoma of the intrathoracic esophagus.

-Surgical resectable carcinoma (T1-4a, N0-3)

-Histologically/ cytologically proven resectable cervical lymph node metastases

-Age > 18 and < 80 years

-European Clinical Oncology Group (ECOG) performance status 0,1 or 2

-Written informed consent

Exclusion criteria

- Distant metastases

- Inadequate pulmonary function disabling transthoracic resection

- Previous neck dissection

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2014
Enrollment:	20

Type: Anticipated

Ethics review

Not applicable
Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 44167
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4430
NTR-old	NTR4552
CCMO	NL48231.041.14
OMON	NL-OMON44167

Study results