T4 Oesophageal Resection.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25753

Source
Nationaal Trial Register

Brief title
TOR

Health condition

Esophageal carcinoma, Esophagectomy, Chemoradiotherapy, T4 tumor

Sponsors and support

Primary sponsor: Academic Medical Center (AMC), Department of Surgery
Source(s) of monetary or material Support: Academic Medical Center (AMC)

Intervention

Outcome measures

Primary outcome

The ability to achieve a radical (R0) resection.

Secondary outcome

1. Toxicity profile of chemoradiotherapy;

2. Adequacy of PET-CT and EUS in (re)staging T4 esophageal carcinoma;

3. Peri-operative morbidity and mortality;

4. Percentage of pathologic complete response;

5. Progression free survival at 6 months.

Study description

Background summary

Rationale:

Current treatment of cT4 (locally irresectable) esophageal carcinoma is subject of debate, but mostly consists of chemoradiotherapy (CRT). However, the results of definite CRT in cT4 esopahgeal carcinoma remain poor with only 20% of patients alive at 3 years after start of CRT and a local recurrence rate up to 60% without any curative options and with an infaust prognosis.
Local control and survival might be improved by surgical resection following CRT for cT4 esophageal carcinoma. Only small series concerning this topic exist at present time, suggesting feasibility and improved local control.

Objective:

To assess the feasibility of surgery following CRT in patients with cT4 esophageal carcinoma with regard to morbidity, mortality and the possibility to achieve a R0 resection.

Study design:

Phase II, non-randomized trial.

Study population:

Patients with cT4 irresectable esophageal carcinoma (adenocarcinoma, squamous cell carcinoma or undifferentiated carcinoma) of the intrathoracic esophagus or gastroesophageal junction, aged >18 <75 years.

Intervention:

Esophagectomy after chemoradiotherapy.

Main endpoints:

The ability to achieve a radical (R0) resection. Secondary endpoint are toxicity profile, adequacy of PET-CT and EUS in (re-)staging T4 esophageal carcinoma, perioperative morbidity and mortality, percentage of pathologic complete response, progression free survival at 6 months.

Study objective

Patients with T4-irresectable carcinoma are generally treated with definitive chemoradiotherapy without curative intent. Considering the positive results of neoadjuvant chemotherapy followed by surgery, we hypothesize that chemoradiotherapy can reduce the size of T4 tumors and allows for surgical resection of the esophagus and an improved survival rate.

Study design

Patients will fill out questionnaires regarding quality of life on 6 occasions; prior to chemoradiotherapy, prior to surgery, 6 weeks postoperatively and 3, 6, 12 months after surgery.

Intervention

Surgery after chemoradiotherapy: Transthoracic esophagal resection (open, right thoracotomy) with en-bloc two-field lymphadenectomy.

Contacts

Public
Postbus 4446
R.L.G.M. Blom
Atrium MC Heerlen afdeling chirurgie, Henri Dunantstraat 5

Heerlen 6401 CX
The Netherlands
+31 (0)45-5766666
Scientific
Postbus 4446

R.L.G.M. Blom
Atrium MC Heerlen afdeling chirurgie, Henri Dunantstraat 5

Heerlen 6401 CX
The Netherlands
+31 (0)45-5766666

Eligibility criteria

Inclusion criteria

1. Histologically proven squamous cell carcinoma, adenocarcinoma or undifferentiated carcinoma of the intrathoracic esophagus or gastroesophageal junction;

2. Surgically irresectable T4 carcinoma as determined by endoscopic ultrasonography (EUS), CT scan or PET-CT of neck, thorax and abdomen, without distant mestastases.

Exclusion criteria

1. cT4 carcinoma with tracheobronchial involvement demonstrated on bronchoscopy after chemoradiotherapy;

2. Past or current history of malignancy other than entry diagnosis except for non-melanomatous skin cancer, or curatively treated in situ carcinoma of the cervix, or malignancy more than 5 years prior to enrollment;

3. Pregnancy (positive serum pregnancy test) and lactation;

4. Clinically significant cardiovascular disease (including myocardial infarction, unstable angina, symptomatic congestive heart failure, serious uncontrolled cardiac arrhythmia) <1 year before enrollment;

5. Active infection or other serious underlying medical condition which would impair the ability of the patient to receive the planned treatment;

6. Dementia or altered mental status that would prohibit the understanding and giving of informed consent;

7. Inadequate caloric and/or fluid intake
Weight loss >15%.

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:	Recruiting
Start date (anticipated):	06-07-2011
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-09-2011
Application type:	First submission

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
NTR-new	NL2914
NTR-old	NTR3060
Other	METC AMC : 11_019
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A