T4 Oesophageal Resection.

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25753

Bron
NTR

Verkorte titel
TOR

Aandoening

Esophageal carcinoma, Esophagectomy, Chemoradiotherapy, T4 tumor

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC), Department of Surgery
Overige ondersteuning: Academic Medical Center (AMC)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The ability to achieve a radical (R0) resection.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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%.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	06-07-2011
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	06-09-2011
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	NL2914
NTR-old	NTR3060
Ander register	METC AMC : 11_019
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A