Pilot study of measuring cardiac volume and cardiac function in patients with resectable esophagus carcinoma during pre-operative chemoradiation

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To assess whether a decrease in heart volume is accompanied by changes in myocardial strain, strain rate, inferior vena cava diameter and blood levels of NT-proBNP and troponins.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational non invasive

Summary

ID

NL-OMON38490

Source
ToetsingOnline

Brief title
Deltastudy chemoradiation esophageal carcinoma

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
esophageal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cardiac volume, esophageal cancer, preoperative chemoradiation, toxicity

Outcome measures

Primary outcome

Change in cardiac volume at baseline compared to weekly measurement during chemoradiation

Secondary outcome

- Change in inferior vena cava diameter at the end of chemoradiation compared to baseline

- Changes in myocardial strain and strain rate at the end of chemoradiation compared to baseline

- Weekly changes in concentration of Creatine Kinase (CK), Creatine Kinase Muscle type and Brain type (CK-MB), troponin, N-terminal-pro-natriuretic peptide (NT-pro-BNP)

- Change in LVEF at the end of chemoradiation compared to baseline

- Change in New York Heart Association (NYHA) score at baseline compared to weekly measurements during treatment.

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Study description

Background summary

The treatment of choice of local resectable esophagus carcinoma is multimodality treatment with chemotherapy, radiotherapy and surgery. In a recently published article from Hagen no postoperative cardiac complications were mentioned, although the heart was partly in the radiation field for the

majority off patients. However, long term cardiac outcome of this regimen is unknown as median follow-up of the study was 45.5 months, Moreover, cardiac outcome has not been a specific focus of interest of this study and was not analysed during chemoradiation. Therefore, subtle signs of emerging cardiac failure may have been missed.
We have recently observed that during 4,5 weeks of pre-operative chemoradiation for esophagus carcinoma the cardiac volume on Computed Tomography (CT) decreased.

Study objective

To assess whether a decrease in heart volume is accompanied by changes in myocardial strain, strain rate, inferior vena cava diameter and blood levels of NT-proBNP and troponins.

Study design

Prospective, single center study

Study burden and risks

Extra time
time for completing questionnaire at baseline and at the end of chemoradiation(total 20 minutes)
time for performing ultrasound of the heart at baseline and at the end of chemoradiation (total 40 minutes)
time for performing electrocardiogram at baseline and at the end of chemoradiation(total 10 minutes)
weekly 1 buis extra bloodcollection (total 22.5 ml)
one extra CT scan at the end of chemoradiation (total 10 minutes)

Extra radiation
extra CT scan (extra radiation 30 mSv)

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

patients with esophageal cancer who are planned to be treated with preoperative chemoradiation

Exclusion criteria

cardiac failure NYHA class 3 and 4
previous radiotherapy

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-04-2013
Enrollment:	23
Type:	Actual

Ethics review

Approved WMO

Date:	20-02-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL42999.018.12