Detection of (sub) clinical toxicity in irradiated vs. non-irradiated surgically treated esophageal cancer patients: a pilot study.

Published: 20-10-2017
Last updated: 12-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational invasive

Summary

ID

NL-OMON44510

Source
ToetsingOnline

Brief title
CROSS SECT study

Condition

- Cardiac disorders, signs and symptoms NEC
- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
cardiopulmonary dysfunction; toxicity heart/lung

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Detection, Esophageal cancer, Radiation, Toxicity

Outcome measures

Primary outcome

As this is an exploratory pilot study to determine the most suitable diagnostic tests for future studies, there will be several endpoints related to (sub)clinical cardiopulmonary dysfunction.

Signs of myocardial ischemia, systolic or diastolic dysfunction, rhythm and valve disorders, pericardial effusion and fibrosis, myocardial fibrosis, focal wall motion disorders and coronary calcifications will be analyzed. The cardiopulmonary (dys)function in EC survivors treated with neo-CRT followed by surgical resection will be compared to cardiopulmonary (dys)function in EC survivors treated with surgical resection alone.

Secondary outcome

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Study description

Background summary

Radiation-induced cardiac and pulmonary toxicity after treatment for intrathoracic tumors is a clinically relevant problem, which may jeopardize the benefit of (neo-adjuvant) (chemo) radiotherapy. Although cure rates are rising since the introduction of neo-adjuvant chemoradiation (neo-CRT) as current standard treatment for esophageal cancer (EC), recent studies showed that there

is a substantial risk of non-cancer treatment-related death in these patients. Furthermore, this risk is underestimated as the cause of death of many patients remains unknown, since the distinction between tumor related and non-cancer related death can be difficult.
Cardiac and pulmonary toxicity and its interaction as seen in pre-clinical studies might explain for these unknown deaths as suggested in several clinical studies.Clinical imaging studies performed shortly after treatment showed changes in different cardiac function parameters, all related to radiation dose parameters. Systematic imaging studies analysing subclinical toxicities at longer follow up have never been performed, most probably because of poor survival rates. However, identification of the magnitude of (subclinical) cardiopulmonary toxicity, by performing several cardiopulmonary function tests, is essential in this patient group as this toxicity is most likely the cause of the increased mortality after thoracic radiotherapy. For future perspectives, these results can be used to select the best diagnostic methods for a prospective cohort study to develop prediction tools for cardiopulmonary toxicity. Finally, this might lead to optimization of radiotherapy dose-distributions (including patient selection for proton therapy) and hopefully reduce radiation induced cardiopulmonary toxicity and improve overall survival.

Study objective

The main objective of this study is to determine the most suitable diagnostic test to identify cardiopulmonary (dys)function in EC survivors treated with neo-CRT followed by surgical resection. Furthermore, we want to estimate the difference in cardiopulmonary (dys)function in EC survivors treated with neo-CRT followed by surgical resection compared to EC survivors who were treated with surgical resection alone.

Study design

Cross-sectional pilot study

Study burden and risks

Several tests will be performed at one time point, 5-10 years after given treatment. If the findings of the test indicate cardiovascular complications, the patient will be referred to the cardiologist for further analysis and/or preventive measures. As one of the tests, cardiac MRI, including gadolinium (Dotarem 0.2 mmol/kg) enhancement will be performed. Potential side effects of gadolinium include brief headache, nausea and dizziness for a brief time following the injection. Allergic reactions are rare. Furthermore, a cardiac CT scan will be performed . With a total radiation exposure of 0.6 mSv (less than a third of the annual background radiation dose), the risks will be minimal.

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

- Treated for EC with a curative resection between 2000 and 2012
- Age >= 18 years
- Written informed consent
- No signs of tumor recurrence or new other malignancies.

Exclusion criteria

- Thoracic radiotherapy for indications other than EC.
- Contra indication for cardiac MRI, pacemaker, cochlear implants, metal not compliable with MRI.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2017
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	20-10-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL61822.042.17
Other	volgt