4D FDG PET-CT imaging in Esophageal cancer

Published: 25-08-2014
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To explore the role of 4D PET-CT in radiation treatment planning, relative to standard 3D PET-CT.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON41189

Source
ToetsingOnline

Brief title
4D FDG PET in esophageal cancer

Condition

- Gastrointestinal neoplasms malignant and unspecified

Synonym
Esophageal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: zijn geen kosten aan het onderzoek.

Intervention

Keyword: 4D FDG PET, Esophageal cancer

Outcome measures

Primary outcome

The estimation of tumor size of the primary esophageal tumor on 4D vs 3D FDG

PET.

Secondary outcome

Measurement of SUV max, SUV mean, and SUV peak in 4D versus 3D images of

esophageal cancer and lymph nodes and number of suspected involved lymph nodes.

Study description

Background summary

FDG PET-CT image acquisition in the abdominal and thoracic region is influenced by organ motion. Respiratory movement blurs the metabolic signal of the esophageal tumor and lymph nodes. We hypothesize that the metabolic signal obtained with motion compensation results in higher SUV-max values and clearer demarcation of the esophageal tumor and lymph nodes.

Study objective

To explore the role of 4D PET-CT in radiation treatment planning, relative to standard 3D PET-CT.

Study design

A pilot study

Intervention

Patients will be imaged with 4D-CT images in addition to the normal protocol of FDG PET-CT image acquisition.

Study burden and risks

For patients, the total radiation burden per PET scan combined with low dose CT images is about 10 mSv. The addition of 4D CT scan adds 50mSv to the total scan. If patients subsequently receives curative chemoradiotherapy, about

0.5-1.0% of the delivered radiation dose to the tumour is inadvertently given to locations near the tumour region. Due to this, the dose directly outside the treated region is about 200-400 mSv due to the treatment of 41.4 Gy radiotherapy. Therefore, the dose increase of 50 mSv due to 4D CT is negligible. Secondary risks associated with radiation exposure are not increased considerably.
Patients that are not eligible for chemoradiotherapy will have distant metastases with a short life expectancy. Therefore, secondary cancer risk from increased radiation exposure is not an issue.

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 pathology proven esophageal cancer or tumor highly suspicious for

esophageal cancer
- >= 18 years
- Wtitten informed consent

Exclusion criteria

- <18 years
- Possibility of pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-03-2015
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	25-08-2014
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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	NL50007.031.14