Early response measurement in non small cell lung cancer.

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To assess tumor reponse with FDG-PET-CT imaging early after start of concomitant chemo-radiotherapy in relation to cytological, histological and biological tumor characteristics. The ultimate goal is to reveal more insight in tumor reponse assesment...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON31456

Source
ToetsingOnline

Brief title
early response measurement

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified
- Respiratory tract neoplasms

Synonym
lung cancer, non-small cell lung cancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: biomarkers, functional imaging, locally advanced lung cancer, non-small cell lung cancer

Outcome measures

Primary outcome

Early response assesment during treatment with concomitant chemo-radiotherapy

for stage III lung cancer with FDG-PET-CT imaging and biological tumor

characteristics.

Secondary outcome

Survival, progression-free survival, toxicity.

Study description

Background summary

Patients with stage III lung cancer are mostly treated with a combination of chemotherapy and radiotherapy. This toxic treatment leads to survival only in a minority of patients. Intensification of treatment schedules for example by concomitant chemoradiotherapy leads to some improvement of survival. Unfortunately this is also accompagnied by increased toxicity. In selected cases survival can be improved by surgery after induction chemo-radiotherapy treatment: only in case of down-staging and Ro resection and if pneumonectomie can be avoided. Assays are needed that can predict tumor response early during treatment to select patients who are responders and will benefit from the treatment and minimize side effects for the non-responders with early modulation of treatment.
Research in other forms of cancer has shown that PET imaging is a usefull tool in recognizing responders and non-responders early during treatment and that a PET guided algorithm can be used in the treatment of cancer patients to modulate therapy.

Study objective

To assess tumor reponse with FDG-PET-CT imaging early after start of concomitant chemo-radiotherapy in relation to cytological, histological and biological tumor characteristics. The ultimate goal is to reveal more insight

in tumor reponse assesment and recognizing responders and and non-responders to concomitant chemo-radiotherapy for stage III lung cancer.

Study design

This is a non-randomized single-centre open label study.

Study burden and risks

Patients included are diagnosed and treated according to normal local standards. For the study they will be subjected to an extra FDG-PET-CT and an extra invasive procedure and an extra bloodsample will be taken on the routine moments for venapunction during this treatment schedule. Patients cannot use a meal prior to these extra investigational procedures. The extra exposure to one extra PET-CT is very low when compared to radiotherapy treatment. The extent of the burden of these extra procedures can be justified by the rationale of this study. Study results are expected to give more insight in tumor response assesment and in recognition of responders and non-responders. We hope this will justify a PET-decision making study in the future to test our hypothesis that tumor response can be assesed shortly after start of treatment leading to an early selection of patients who will benefit of the treatment and patients whom an unnescecarry toxic treatment can be withheld.

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

stage III with cytologically or histologically proven N2 or N3 disease or T4 patients who are to be treated with concomitant chemoradiotherapy
age 18-70
performance status ECOG 0-1
no contraindications for chemo-radiotherapy, surgery or diagnostic procedures

Exclusion criteria

pregnancy
previous radiotherapy to the chest

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2008
Enrollment:	50

Type:	Anticipated

Ethics review

Approved WMO Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL20237.091.08