Dynamic FDG-PET/CT response during chemoradiation for NSCLC

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General objective:• Determine the prognostic value of T50 for treatment outcome of CCRT for NSCLC.Secondary objectives:• S1: Confirm the image quality of extremely low dose FDG PET/CT scans.• S1: Test the complex study logistic with all involved...

Ethical review	Approved WMO
Status	Pending
Health condition type	Respiratory tract neoplasms
Study type	Observational invasive

Summary

ID

NL-OMON39496

Source
ToetsingOnline

Brief title
PET response during chemoradiation of lung cancer

Condition

- Respiratory tract neoplasms

Synonym
lung cancer

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: CTMM Airforce

Intervention

Keyword: FDG PET/CT, NSCLC, radiotherapy, response monitoring

Outcome measures

Primary outcome

• The main study parameter is the maximum FDG uptake (SUVmax) at the location of the primary tumour, as determined at multiple days during treatment (up to five time points per patient), expressed as T50 for response evaluation.

• The main study endpoint is progression free survival, to be correlated with T50 for prognostic value.

Secondary outcome

Secondary study parameters/endpoints

• Increase SUVmax during de first two weeks of treatment, indicating inflammatory response.

• Increase SUVmax between diagnostic imaging and day 1, indicating potential progression.

Other study parameters

Available image sets will be evaluated using several other diagnostic methods. This will not contribute to the main study outcome, but may yield interesting additional knowledge and potential new strategies for outcome prediction.

• Anatomical response based on RECIST criteria.

• Biological response based on EORTC criteria.

• Alternative T50 based on SUVmean of the primary tumour.

• Alternative T50 based on SUVpeak of the primary tumour.

• Alternative T50 based on SUVmax/mean of nodal metastases in the imaging range.

• Voxel-based evaluation to identify intra-tumoural differences in response.

Study description

Background summary

The treatment of inoperable non-small cell lung cancer (NSCLC) is radiotherapy with concurrent chemotherapy, 24 fractions of 2.75 Gy (66Gy) combined with concurrent Cisplatin 6 mg/m2. However with curative intent, only a small percentage will survive. This study aims to determine the optimal time point to measure response during CCRT as a base to change treatment.

Study objective

General objective:
• Determine the prognostic value of T50 for treatment outcome of CCRT for NSCLC.

Secondary objectives:
• S1: Confirm the image quality of extremely low dose FDG PET/CT scans.
• S1: Test the complex study logistic with all involved departments (nuclear medicine, outpatient clinic, radiotherapy).

• S2: Determine the shape of the FDG response curve during CCRT for NSCLC.
• S2: Determine occurrence and timing of an early inflammatory response to CCRT.
• S2: Determine the variation between the SUVmax at diagnostic PET/CT and day 1 of treatment.
• S2: Determine the distribution in time of T50 in the specified patient group.
• S2: Define an optimal measurement strategy for T50 during CCRT.

• S3: Determine the prognostic value of T50 with regard to local and regional control.

Study design

In Stage 1 of the study, 2 pilot patients will undergo 1 extra PET/CT scan, the first to confirm the image quality of extremely low dose FDG scans and the second to test the complex study logistic with all involved departments.

In the second stage to a maximum of 40 patients, five FDG PET/CT scans during treatment and one for follow up will be added to the normal diagnostic

procedures as a part of this study. Changes in the SUVmax will be measured, to determine the FDG response curve, inflammation peak, and mean T50.

Providing a succesful result of Stage 2, about another 40 patients in Stage 3 will undergo less than 6 scans to correlate the T50 with progression free survival, to determine the prognostic value. For this third Stage an amendment will then be written and started after permission of the PTC of the NKI-AVL. Also an amendement for the ABR form will be made.

Study burden and risks

No is expected from the FDG injections or the PET/CT scans (however a small amount of radiation dose will be given).
The logistical burden for the patients is 6 hours fasting plus 1.5 hour extra in the NKI-AVL on all days of PET imaging.
No additional IV access is needed. All FDG, saline and Cisplatin can be administered using the same IV cannula, that would already be placed for standard CCRT or follow up CT-scan. The time in the hospital will be as short as possible by giving the saline of the outpatient clinic during FDG biodistribution.

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

• Cytologically or histologically proven NSCLC
• T2-4 N0-3 M0 disease (stage II or III, inoperable)
• Scheduled for standard concurrent chemoradiation
• Primary tumour minimal diameter 3 cm
• Primary tumour SUVmax > 5 on routine diagnostic pre-treatment FDG PET/CT
• WHO performance 0-1
• Written informed consent according to GCP and national regulations

Exclusion criteria

• Age < 18 years
• Incapacitated subjects
• Pregnant or lactating women
• Diabetes Mellitus
• Participation in dose escalation studies
• Other neoplasms with metastases in the last 3 years

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2012

Enrollment:	42
Type:	Anticipated

Ethics review

Approved WMO Date:	21-11-2012
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	23-10-2013
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	09-01-2014
Application type:	Amendment
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	NL39209.031.12