F-FDG PET as an Early Response Parameter in Stereotactic Body Radiotherapy for stage I-II (T1-T3, N0) Non Small Cell Lung Carcinoma: A Pilot Study

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The objective of the present study is to investigate whether a metabolic response as assessed by 18F-FDG PET can be observed after the first fraction of SBRT. This study will contribute to establishing the role of definitive SBRT in the treatment of...

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

Summary

ID

NL-OMON32072

Source ToetsingOnline

Brief title RT2007-04

Condition

Respiratory tract neoplasms

Synonym

Non small cell lung carcinoma; lung cancer

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: F-FDG PET, Non Small Cell Lung Carcinoma, Stereotactic radiotherapy

Outcome measures

Primary outcome

1. The metabolic response after the first fraction

Secondary outcome

- 1. The metabolic response 12 weeks after completion of SBRT
- 2. The intra-individual dynamics between these scans
- 3. Tumor response on CT-thorax according to RECIST-criteria 12 weeks after

completion of SBRT

Study description

Background summary

Lobectomy is considered treatment of choice for stage I/II NSCLC [28]. Non surgical treatments are offered to medically inoperable patients or those who refuse surgery. Conventionally fractionated radiotherapy is frequently offered to this selected patient population, however, it results in poor local control and overall survival rates. Stereotactic body radiotherapy (SBRT) is a relatively new approach in the treatment of NSCLC. This technique utilizes precise radiation delivery, enabling the delivery of biological doses > 100 Gy, in 3-8 fractions. It results in local control rates comparable to those obtained with surgery. Therefore, SBRT has become standard treatment for patients with stage I-II NSCLC.

At the moment tumour response is assessed 12 weeks after SBRT. A CT-thorax is used to measure size, and an 18F-FDG PET scan is used to evaluate the *metabolic response* of the tumour. An early metabolic response, i.e. the metabolic response already during treatment, has shown to select patients with different outcomes. Whether an early response occurs during SBRT for NSCLC is unknown, and is subject of the present study.

Study objective

The objective of the present study is to investigate whether a metabolic response as assessed by 18F-FDG PET can be observed after the first fraction of SBRT. This study will contribute to establishing the role of definitive SBRT in the treatment of stage I/II NSCLC.

Study design

Observational pilot study

Study burden and risks

To administer 18F-FDG, patients will receive an IV catheter. This may result in local tenderness and bruising afterwards.

The radiation dose of a single 18F-FDG PET scan has been calculated at 7 mSv. Thus, the extra radiation dose received for the purpose of this study is 7 mSv. This dose is negligible when compared to the radiotherapy dose given (i.e. approximately 60.000 mSv). Although the comparison between absorbed local irradiation (SBRT) and total body irradiation (18F-FDG PET scan) is difficult, we assume that the extra radiation of the 18F-FDG PET scan is not hazardous for the patients.

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

T1-T3, N0, M0 Adequate pulmonary function Medically inoperable or refused surgery Life expectancy of at least 6 months Histological conformation of non-small cell lung cancer or a F-FDG positive, growing mass on CT-thorax, suggestive of NSCLC

Exclusion criteria

Disease other than T1-T3, N0 M0 Inadequate pulmonary function Life expectancy less than 6 months

Study design

Design

Study phase:2Study type:Observational non invasiveMasking:Open (masking not used)Control:UncontrolledPrimary purpose:Treatment

Recruitment

 NL

4 - F-FDG PET as an Early Response Parameter in Stereotactic Body Radiotherapy for s ... 4-05-2025

Recruitment status:	Pending
Start date (anticipated):	01-12-2007
Enrollment:	10
Туре:	Anticipated

Ethics review

Approved WMO Application type: Review commission:

First submission 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 CCMO

ID NL20140.042.07