Reproducibility of FDG PET scans in patients with lung cancer.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21780

Source
Nationaal Trial Register

Brief title
FDG reproducibility

Health condition

NSCLC
Reproducibility
FDG PET

Sponsors and support

Primary sponsor: VU University medical centre (VUmc) Amsterdam
Source(s) of monetary or material Support: VU University medical centre (VUmc) Amsterdam

Intervention

Outcome measures

Primary outcome

Reproducibility of various SUV measures, metabolic and anatomic volume measurements on whole body [18F]FDG PET-CT. Test-retest variability will be calculated and expressed in terms

of intraclass correlations and Bland-Altman analysis. Two-sided paired t-test and correlation analysis will be performed to asses the significance of any differences in the outcome measurements (SUV and volume).

Secondary outcome

To evaluate reproducibility of the variables as a function of the [18F]FDG time uptake interval.

Study description

Background summary

Rationale:

To detect changes in multiple [18F]fluorodeoxyglucose positron emission tomography – computed tomography ([18F]FDG PET-CT) scans in one patient, test-retest variability needs to be determined, to know when an observed difference is due to a true biological effect.

Objective:

The aim of the present study is to further measure the test-retest reproducibility of [18F]FDG PET-CT whole body scans in non-small cell lung cancer (NSCLC) patients. In this study the impact of using different tracer uptake periods and use of state of the art PET-CT technology of tracer uptake quantification and delineation using various new methodologies will be explored. Moreover, test-retest variability of 1D, 2D and volumetric tumor size measurements will be assessed.

Study design:

Monocentre, prospective observational study including 12 eligible patients with NSCLC who will be scanned with [18F]FDG on two separate occasions (within one week), without intervening therapy. Personal characteristics will be registered (age, sex, bodyweight, height).

Study population:

Patients with histological proven NSCLC, stage IIIB or IV.

Intervention:

The procedure consists of intravenous administration of [18F]FDG and PET-CT scanning. This procedure will be repeated within a maximum of 7 days (test-retest design).

Main study parameters/endpoints:

Reproducibility of standardized uptake value (SUV), metabolic and anatomic volume measurements on whole body [18F]FDG PET-CT.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

The total amount of radiation burden is 26 mSv.

Study time-course:

We expect to complete the patient inclusion in 6 months; data analysis and writing will require 3 months.

Statistical analysis:

Intraclass correlations and Bland-Altman analysis will be performed to evaluate reproducibility between the two scans.

Study objective

Reproducible test-retest assessment of [18F]FDG PET.

Study design

Taken together we expect to complete the patient inclusion in 6 months; data analysis and writing will require approximately 3 months.

Intervention

[18F]FDG PET at two seperate timepoints.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patient age 18 years or older;

2. Histological diagnosis of NSCLC, stage IIIB or IV;

3. At least one tumour with diameter > 3cm (to minimize partial volume effects);

4. Able to remain supine for 60 minutes in the PET-CT scanner;

5. Written informed consent.

Exclusion criteria

1. Chemotherapy in the past 4 weeks;

2. Pregnant or lactating patients;

3. Metal implants (e.g. pacemakers);

4. Weight of more than 100 kg;

5. Known diabetes mellitus type I and II.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2012
Enrollment:	12
Type:	Anticipated

Ethics review

Positive opinion

Date:	05-07-2012
Application type:	First submission

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
NTR-new	NL3360
NTR-old	NTR3508
Other	METC VUmc : 2012/148
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A