Reproducibility of FDG PET scans in patients with lung cancer.

Gepubliceerd: 05-07-2012 Laatst bijgewerkt: 13-12-2022

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21780

Bron
NTR

Verkorte titel
FDG reproducibility

Aandoening

NSCLC
Reproducibility
FDG PET

Ondersteuning

Primaire sponsor: VU University medical centre (VUmc) Amsterdam
Overige ondersteuning: VU University medical centre (VUmc) Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

[18F]FDG PET at two seperate timepoints.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-08-2012
Aantal proefpersonen:	12
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	05-07-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3360
NTR-old	NTR3508
Ander register	METC VUmc : 2012/148
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A