Test-retest reproducibility of whole body [18F]FDG PET-CT in patients with malignant lung lesions.

Published: 06-06-2012
Last updated: 01-05-2024

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...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Metastases
Study type	Observational invasive

Summary

ID

NL-OMON39195

Source
ToetsingOnline

Brief title
PET-CT test-retest in patients with malignant lung lesions

Condition

- Metastases

Synonym
advanced stage cancer, metastatic cancer

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cancer, FDG, PET-CT, Reproducibility

Outcome measures

Primary outcome

Reproducibility of various SUV measures, metabolic and anatomic volume

measurements on whole body [18F]FDG PET-CT.

Secondary outcome

Not applicable.

Study description

Background summary

Positron emission tomography (PET) is a non-invasive imaging technique based on the use of biologically relevant compounds labelled with short-lived positron-emitting radionuclides such as carbon-11, nitrogen-13, oxygen-15 and fluorine-18.

With the introduction of hybrid machines, combining PET and computed tomograpgy (PET-CT), and in the near future PET and magnetic resonance imaging (PET-MRI), it is possible to evaluate integrated metabolic and anatomic images. This has a high impact in diagnosing cancer and evaluating response to therapy.

To detect changes in multiple [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. For response evaluation, PET Response Criteria in Solid Tumors (PERCIST) have been published with a suggested threshold of 30% decline in SUV for partial response, and 30% increase for progressive disease [J Nucl Med. 2009 May;50 Suppl 1:122S-50S.]. These thresholds are based on performed test-retest studies with different types of cancers and different scanner acquisitions and types (mainly PET alone).

Repeatability of SUV measurements have been evaluated in advanced gastrointestinal malignancies by Velasquez et.al [J Nucl Med. 2009 Oct;50(10):1646-54] resulting in a threshold of 34% decrease and 52% increase for determining true metabolic changes.
In non small-cell lung cancer (NSCLC) test retest reproducibility has been

tested by Hoekstra et.al. [J Nucl Med. 2002 Oct;43(10):1304-9] with a dynamic [18F]FDG PET only scan. This study showed an intraclass correlation coefficient of 0.95 for full kinetic analysis (nonlinear regression (NLR)).
Nahmias et.al. [J Nucl Med. 2008 Nov;49(11):1804-8] published the results of a test-retest study with a variety of cancer types (including NSCLC) with whole body [18F]FDG PET-CT, with a threshold of an absolute decrease of 0.5 in SUV mean for response evaluation. In addition to the test-retest repeatability, the interaction of the (newer) anticancer drugs with the tracer pharmacokinetics should be taking into account for evaluating response to treatment in the future. Reproducibility of multiple lesions and including metabolic volume in the analysis has never been performed to our knowledge.

To date the optimal tracer uptake time is still matter of debate (60 versus 90 min p.i.). Moreover, test-retest (TRT) data is primarily based on (outdated) PET technology and assessment of TRT for state of the art PET/CT systems is limited. Finally, several new and extra PET/CT based quantitative tracer uptake measures have been developed in our institute and are becoming more widely available, such as SUV based on several new PET based delineation methods [J Nucl Med. 2011 Oct;52(10):1550-8.], total lesion glycolysis, metabolic volume [J Nucl Med. 2010 Dec;51(12):1870-7.] and tracer uptake heterogeneity assessment [Eur J Nucl Med Mol Imaging. 2011 Sep;38(9):1636-47]. Yet, there is no or very limited data on the TRT performance of these new and upcoming metrics. The purpose of the study is to collect TRT FDG PET images using current state of the art PET-CT technology to allow for the assessment of TRT performance of several new quantitative tracer uptake measures that became feasible for clinical use that have emerged through the development of PET-CT technology.

To our knowledge no study has been published evaluating the reproducibility of whole body [18F]FDG PET-CT for malignant lung lesions with two time intervals (60 and 90 min) postinjection to evaluate test-retest reproducibility of a wide variety of quantitative tracer uptake measures and to determine the best time-interval for scanning post-injection.

Study objective

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.The aim of the present study is to further measure the test-retest reproducibility of [18F]FDG PET-CT whole body scans in patients with malignant lung lesions. 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

This study is a single centre, prospective observational study. 12 eligible patients with malignant lung lesions will be included and will undergo two [18F]FDG PET-CT scans on two separate occasions (within one week), without intervening therapy. The whole body PET scans will be performed on a Philips Gemini TF PET-CT scanner. Personal and tumour characteristics will be registered (age, sex, body weight, body height and medication).

Study burden and risks

The venous cannulas will be placed by highly qualified medical doctors of the Department of Nuclear Medicine & PET Research. In spite of this, occasionally these cannulas may cause a hematoma. A PET scan is a regular diagnostic imaging technique. Each study will be conducted in compliance with the radiation safety guidelines of the department. Based on results we obtained from biodistribution studies in rats, whole body radiation after intravenous injection of 185 MBq [18F]FDG is approximately 8 mSv, including the low dose CT used for attenuation correction. Patients will undergo two [18F]FDG PET scans, together with a diagnostic CT thorax with intravenous contrast (5 mSv). The total amount of radiation burden will be approximately 26 mSv during the entire study. To compare, every person living in the Netherlands receives a natural background radiation dose of 2-2,5 mSv per year.

We are aware that the radiation burden for this study is high, but are of the opinion that this is acceptable for this particular study (with this specific population and high scientific impact). Patients will very likely receive chemoradiation therapy as part of the best standard of care. The radiation burden from the treatment will be a multitude higher than the radiation dose from the diagnostic work-up and the presently suggested TRT study. In addition, the results of this study will have great clinical benefit in using [18F]FDG PET-CT as response evaluation tool in the future, improving personalized therapy strategies for cancer patients. We therefore consider the additional radiation burden acceptable and we feel that it outweighs the scientific merit of results that come from the suggested study.

Contacts

Public
Vrije Universiteit Medisch Centrum

de Boelelaan 1117
Amsterdam 1081 HV
NL

Scientific
Vrije Universiteit Medisch Centrum

de Boelelaan 1117
Amsterdam 1081 HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Malignant lung lesions (of any primary)
18 years and older
Expected life expectancy of < 8 year
Tumor larger than 3 cm diameter
written informed consent

Exclusion criteria

Pregnant or lactating
Known diabetes mellitus type I and II
Chemotherapy during past 4 weeks

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):	22-01-2013
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO Date:	06-06-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-08-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL40157.029.12