TEST-RETEST REPRODUCIBILITY OF PET-CT USING RADIOLABELLED WATER (H2[15]O) IN PATIENTS WITH NON-SMALL-CELL LUNG CANCER

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To measure the test-retest reproducibility of tumor blood flow and associated measurements as measured with H2[15]O PET-CT in patients with non-small-cell lung cancer.

Ethical review	Approved WMO
Status	Pending
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON31900

Source
ToetsingOnline

Brief title
H2O-PET test-retest

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym
non-small-cell lungcancer

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: H2[15]O, NSCLC, PET-CT, Reproducibility

Outcome measures

Primary outcome

Tumor blood flow

Secondary outcome

Tumor volume of distribution

Study description

Background summary

With the arrival of molecular-targeted therapeutics for cancer treatment, questions arise which tool is best for response monitoring. The most promising drugs in this category target VEGF and/or EGFR and are also called antivascular or antiangiogenic agents. Since these agents do not regularly result in cell kill, their effect results in consolidation of the tumor mass rather than regression. Therefore, the standard volumetric approach (RECIST) is not suitable. H2[15]O PET-CT offers the opportunity to measure tumor blood flow, and seems to be a perfect tool to monitor response and effects to these new agents. To interpret future results, test-retest reproducibility needs to be known. In the oncological setting only two inhalation PET studies have been performed in a limited number of patients and range of tumors (mainly hepatic lesions). Test-retest results of hepatic tumors cannot be directly translated to tumors of other origin, due to their dual blood supply. Integrated PET-CT allows to perform a H2[15]O PET-CT study in approximately 30 minutes. This minimizes patient burden when compared to a *traditional* PET-scanner where, besides a transmission scan, a tissue-accumulating tracer is needed for adequate ROI definition, adding 70 minutes to the acquisition protocol.

Study objective

To measure the test-retest reproducibility of tumor blood flow and associated measurements as measured with H2[15]O PET-CT in patients with non-small-cell lung cancer.

Study design

A prospective study in 20 patients with NSCLC who will be scanned twice on one day with a minimal time-interval of four hours without intervening therapy. The dynamic H2[15]O PET scan will be preceded by a low-dose thoracic CT scan for photon attenuation correction and ROI definition. A venous cannula will be inserted for administration of the PET tracer. Total scan time will be 60 minutes (2 x 30 minutes).

Study burden and risks

The venous cannula can cause a hematoma.

The effective dose equivalent of 1100 MBq H2[15]O is 1.2 mSv, while the low-dose thoracic CT scan accounts for 0.9 mSv. The total delivered dose will be 4.2 mSv for both scans (2.1 mSv per scan). The average annual radiation load per person in the Netherlands from the environment measures 2.3 mSv.

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

Diagnosis of highly suspected or proven NSCLC
Age equal to or above 18 years
Tumour diameter equal to or largen than 3cm (to minimize partial volume effects)
Able to remain supine for 15 minutes

Exclusion criteria

Previous chemotherapy for last 3 months
Previous thoracic radiotherapy
Pregnancy
No informed consent

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2007
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
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	NL19977.029.07