Een studie naar farmacokinetiek en reproduceerbaarheid van 18Fluor - gelabelde choline in patienten met prostaat kanker.

No registrations found.

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

Summary

ID

NL-OMON26086

Source
NTR

Brief title
[18F]FCH pharamcokinetics and repeatability

Health condition

Keywords
English: pharmacokinetics, repeatability, PET, choline, prostate cancer, kinetic model, standardised uptake value (SUV), region of interst (ROI), volume of interest (VOI).
Dutch: farmacokinetiek, reproduceerbaarheid, PET, choline, prostaat kanker, kinetiek model, SUV, ROI, VOI.

Sponsors and support

Primary sponsor: VU University Medical Center, Amsterdam , The Netherlands.
Source(s) of monetary or material Support: Sponsor, the above.

Intervention

Outcome measures

Primary outcome

Part A:

A pharmacokinetic model for [18F]FCH.

Part B:

Test-retest variability of the simplified method of choice (part A) implemented in WB [18F]FCH PET-CT.

Secondary outcome

Part A: Selection of an appropriate simplified quantitative method for use of [18F]FCH in clinical practice.

Study description

Background summary

Rationale:

[18F]Fluoromethylcholine ([18F]FCH) is a relatively new oncological tracer used to perform Positron Emission Tomography – Computed Tomography ([18F]FCH PET-CT) scans. Choline, a precursor of the phospholipids, expresses the cell membrane synthesis which is enhanced in carcinogenesis. Presently, the main application of this tracer is restaging in patients with prostate cancer (PCa). For response evaluation, accurate quantification of the [18F]FCH signal is important beyond visual image interpretation. For quantification of PET tracers, non-linear regression analysis is the gold standard. However, its complexity makes it unsuitable for application in daily clinical practice; moreover, it is not compatible with the whole body acquisitions typically required in patients with metastasised disease. Simplified measures applicable in whole body settings can be validated versus the reference technique. Finally, to allow proper interpretation of signal changes over time, the repeatability of the simplified method of choice should be defined. A better knowledge of the pharmacokinetics and repeatability data of choline could lead to an optimization of the [18F]FCH PET-CT diagnostic potential. This will improve personalized therapy strategies for prostate cancer patients.

Objective:

The aims of the present study are: 1. to create a tracer kinetic model for quantification of [18F]FCH and simultaneously validate a simplified quantitative method, and 2. to assess the repeatability of the latter method.

Study design:

A monocenter, prospective observational study in patients with metastasized prostate cancer. The study consists of two parts: part A, the [18F]FCH pharmacokinetics, and part B, the repeatability of [18F]FCH estimates.

A. In the first part, both cell membrane proliferation ([18F]FCH) and perfusion (H215O) will be measured quantitatively. Accuracy of blood and plasma activity concentration, plasma metabolite measurements derived from arterial and venous samples as well the reliability of using Image Derived Input Functions (IDIF) for quantification of [18F]FCH kinetics will be tested. Dynamic scanning will be performed on one occasion, using 2 tracers: H215O and [18F]FCH.

B. In the second step of the protocol, depending on the obtained validation in part A, the repeatability of the method will be tested in patients, on two separate occasions using a whole body (WB) [18F]FCH PET-CT scan.

Study population:

Patients with histologically proven metastasised prostate carcinoma.

Intervention:

Part A procedure consists of a PET study after intravenous (iv) administration of H215O, followed by a second PET study directly after [18F]FCH administration, together with arterial and venous blood sampling during the PET-CT scanning. The dynamic scan is performed over a relevant body region, directly post injection (p.i.) of each of the tracers. Furthermore, analysis of arterial and venous samples will be performed, in order to ensure that arterial and venous samples provide the same information for calibrating and correcting input functions for use of [18F]FCH kinetic quantification. Part B procedure consists of iv administration of [18F]FCH and a WB PET-CT scan. This procedure will be repeated within a maximum of 7 days.

Main study parameters/endpoints:

Part A: A pharmacokinetic model for [18F]FCH and an appropriate simplified quantitative method.

Part B: Test-retest variability of the simplified method of choice (part A) implemented in WB [18F]FCH PET-CT.

Study objective

Part A: In clinical practice the use of simplified quantitative methods and procedures can be fully validated against complex quantitative kinetic measures.

Part B: Test-retest repetability of different SUV measures, metabolic and anatomic volume measurements can be implemented on whole body [18F]FCH PET-CT.

Study design

Part A:

10 minutes dynamic scan after injection of a perfusion tracer, followed by a 40 minutes dynamic scan after iv administration of [18]FCH.

Part B:

40 minutes whole body PET-CT after administration of [18F]FCH at a timepoint to be deducted from Part A.

Intervention

This is a single centre, prospective, observational study in patients with metastasized Prostate cancer.

Part A:

Performing of dynamic scans of the target region involving metstases, together with analysis of arterial and venous samples.

Part B:

Intravenous administration of [18F]FCH and performing a static PET-CT scan. This procedure will be repeated within one week.

Contacts

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Eligibility criteria

Inclusion criteria

Part A:

1. Histologically proven prostate cancer, with lymphatic and/or haematogeneous metastases;

2. Written informed consent;

3. At least 2 tumours (metastases) per patient detected by conventional imaging (e.g., bone scan, either CT or MRI of the chest, abdomen and pelvis); conventional imaging should be recently performed (no longer than 3 months previous to the PET-CT scan);

4. At least one tumour (metastasis) with diameter 1.5 cm (to minimize partial volume effects);

5. Patients able to remain supine for 50 minutes in the PET-CT scanner.

Part B:

1. Histologically proven prostate cancer, with lymphatic and/or haematogeneous metastases;

2. Written informed consent;

3. At least one tumour (metastasis) with diameter > 1.5 cm detected by recently performed conventional imaging (maximal 3 months prior to the PET-CT scan);

4. Patients able to remain supine for 40 minutes in the PET-CT scanner.

Exclusion criteria

1. Claustrophobia (part A and B);

2. Multiple malignancies (part A and B);

3. Anticoagulant therapy (part A).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2012
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	16-05-2012
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	NL3288
NTR-old	NTR3434
Other	EudraCT : 2012-002442-20
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A