

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

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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 repeatability of different SUV measures, metabolic and anatomic volume...

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

Samenvatting

ID

NL-OMON26086

Bron

NTR

Verkorte titel

[18F]FCH pharmacokinetics and repeatability

Aandoening

Keywords

English: pharmacokinetics, repeatability, PET, choline, prostate cancer, kinetic model, standardised uptake value (SUV), region of interest (ROI), volume of interest (VOI).

Dutch: farmacokinetiek, reproduceerbaarheid, PET, choline, prostaat kanker, kinetiek model, SUV, ROI, VOI.

Ondersteuning

Primaire sponsor: VU University Medical Center, Amsterdam , The Netherlands.

Overige ondersteuning: Sponsor, the above.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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 repeatability of different SUV measures, metabolic and anatomic volume measurements can be implemented on whole body [18F]FCH PET-CT.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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 metastases, 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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Claustrophobia (part A and B);
2. Multiple malignancies (part A and B);
3. Anticoagulant therapy (part A).

Onderzoeksopzet

Opzet

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

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2012
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	16-05-2012

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	NL3288
NTR-old	NTR3434
Ander register	EudraCT : 2012-002442-20
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A