A study on the pharmacokinetics and repeatability of [18F]Fluoromethylcholine PET-CT in patients with prostate cancer

Published: 19-06-2012
Last updated: 26-04-2024

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.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Observational invasive

Summary

ID

NL-OMON39240

Source
ToetsingOnline

Brief title
[18F]FCH pharmacokinetics and repeatability

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
prostate cancer, prostate malignancy

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: [18F]FCH PET-CT, pharmacokinetics, prostate cancer, repeatability

Outcome measures

Primary outcome

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.

Secondary outcome

To identify an appropriate simplified quantitative method for clinical

practice.

Study description

Background summary

[18F]Fluoromethylcholine ([18F]FCH) is a relatively new oncological tracer used to perform Positron Emission Tomography * Computed Tomography ([18F]FCH PET-CT) scans.
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.

Study 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 20 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 in eight patients. 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 12 other patients, on two separate occasions (at most one week apart) using a whole body (WB) [18F]FCH PET-CT scan.

Study burden and risks

The total amount of radiation burden will be lower than 4.5 mSv during the entire part A study. The total amount of radiation burden for part B will not exceed 14 mSv.

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

Part A:
1. Histologically proven metastasised prostate cancer
2. Written informed consent
3. At least 2 tumours (metastases) per patient detected by conventional imaging (e.g., bone scan, CT or MRI of the chest, abdomen or pelvic region); conventional imaging should be recently performed (no longer than 3 months previous to the PET-CT scan)
4. At least one tumour (metastasis) with a diameter equal or more than 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 metastasised prostate cancer
2. Written informed consent
3. At least one tumour (metastasis) with a diameter equal or more than 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 60 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 invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-09-2012
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	[18F]Fluoromethylcholine
Generic name:	[18F]Fluoromethylcholine

Ethics review

Approved WMO Date:	19-06-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-08-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-07-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	02-08-2013
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
EudraCT	EUCTR2012-002442-20-NL
CCMO	NL40899.029.12