A Prospective Study on 18F-DCFPyL PET/CT Imaging in Biochemical Recurrence of Prostate Cancer

Published: 09-04-2020
Last updated: 08-04-2024

The primary study objective is to compare: - Per-patient detection rate of 18F-DCFPyL PET/CT versus that of 18F-FCH PET/CT. The secondary objectives are to assess: - Impact on patient treatment/management. - Per-region detection rate of 18F-DCFPyL...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON55231

Source
ToetsingOnline

Brief title
PYTHON

Condition

- Other condition
- Endocrine neoplasms malignant and unspecified

Synonym
Biochemical recurrent prostate cancer, prostate cancer

Health condition

Biochemical recurrent prostate cancer

Research involving
Human

Sponsors and support

Primary sponsor: Curium PET France
Source(s) of monetary or material Support: Curium PET France

Intervention

Keyword: 18F-DCFPyL, 18F-Fluoromethylcholine, PET/CT scan, Prostate cancer

Outcome measures

Primary outcome

Primary endpoint:

Per-patient detection rate of 18F-DCFPyL PET/CT and 18F-FCH PET/CT for recurrence (either local, regional or distant), based on the independent central reading. The detection rate is defined as the ratio between the number of patients defined as positive at patient level by at least 2 independent readers, and the total number of assessed patients.

Secondary outcome

Secondary endpoints:

- Impact on patient treatment/management.

- Per-region detection rate of 18F-DCFPyL PET/CT versus that of 18F-FCH PET/CT.

- Sensitivity and specificity of 18F-DCFPyL PET/CT versus that of 18F-FCH PET/CT on a per-patient and per-region basis, using composite SOR.

- Concordance rate between 18F-DCFPyL PET/CT and 18F-FCH PET/CT for regions using composite SOR.

- Safety of 18F-DCFPyL versus that of 18F-FCH

Ten regions will be assessed:

- prostate bed (T),

- pelvic lymph nodes (N),

- retroperitoneal lymph nodes, supradiaphragmatic lymph nodes (M1a),

- bone (M1b), five subcategories will be assessed: *spine*, *ribs, sternum and

scapula*, *iliac and sacrum*, *femurs and humerus*, *others*,

- other organ (M1c).

Study description

Background summary

Prostate cancer (PCa) is recognized as one of the principal medical problem the male population is facing. Most men dying of prostate cancer succumb to metastatic and/or recurrent disease. Moreover, rising PSA after initial definitive therapy (known as biochemical recurrence (BCR) of PCa) may occur in 20-30% of prostate cancer patients within 5 years, before a more definitive diagnosis of metastatic disease can be established by conventional imaging modalities. The key question in case of BCR remains whether the PSA rise is reflective of locally confined recurrence or is caused by distant metastatic disease. Correct identification is essential for further treatment planning because, in local recurrence or loco regional lymph node metastasis, potentially curative local treatment may still be possible, whereas in distant metastasis, watchful waiting or eventually (palliative) systematic treatment should be considered.

While identification of biochemical recurrence (BCR) post therapy can be achieved with the prostate specific antigen (PSA) test, localization of recurrence can be challenging with conventional imaging modalities, like MRI or CT scans, that can*t match the sensitivity of this blood test.

PET-CT has overcome many limitations of conventional imaging, resulting in more accurate assessment of patients with BCR. With a new class of positron emission tomography (PET) radiopharmaceuticals targeting the prostate specific membrane antigen (PSMA), it has become feasible to detect recurrent or metastatic prostate cancer that is otherwise occult on conventional imaging modalities. PSMA is a transmembrane glycoprotein expressed by virtually all prostate cancers, and its expression is further increased in metastatic and

hormone-refractory prostate carcinomas.
Various radiolabeled anti-PSMA monoclonal antibodies have been used to detect prostate cancer nodal metastasis and recurrence. 18F-DCFPyL is a radiolabeled small molecule that binds to the extracellular domain of prostate-specific membrane antigen (PSMA) with high affinity.

In this study, we aim to determine the detection rate of 18F-DCFPyL PET/CT in patients with first biochemical recurrence and assess the clinical impact of 18F-DCFPyL PET/CT in patient management and to evaluate the safety of this radiopharmaceutical for clinical use.

Study objective

The primary study objective is to compare:
- Per-patient detection rate of 18F-DCFPyL PET/CT versus that of 18F-FCH PET/CT.

The secondary objectives are to assess:
- Impact on patient treatment/management.
- Per-region detection rate of 18F-DCFPyL PET/CT versus that of 18F-FCH PET/CT.
- Sensitivity and specificity of 18F-DCFPyL PET/CT versus that of 18F-FCH PET/CT on a per-patient and per-region basis, using a composite SOR.
- Concordance rate between 18F-DCFPyL PET/CT and 18F-FCH PET/CT for regions using a composite SOR.
- Safety of 18F-DCFPyL versus that of 18F-FCH

Study design

This is a prospective, open label, cross-over, comparative study. The study population is diagnosed in the past with histopathologically confirmed prostate adenocarcinoma, for which curative therapy is received. The results of the PSA test suspects that the patient has biochemical recurrence of prostate cancer, defined by:
- PSA * 0.2 ng/mL confirmed by a subsequent PSA value of *0.2 ng/mL, if the patient has previously been treated by radical prostatectomy +/- eLND,
- Rise of PSA > 2 ng/mL above the nadir after therapy, regardless of the serum concentration of the nadir, if the patient has previously been treated by curative radiation therapy (EBRT or brachytherapy).

Patients are randomized to determine the order of the 2 radiodiagnostic agents to be used.
The evaluation of the PET / CT scans will be performed blinded by a central reading center.

Intervention

In this study, 2 radiodiagnostic tracers, intravenously administered, will be used:
- 18F-DCFPyl
- 18F-Fluoromethylcholine.

Study burden and risks

Biochemical recurrence (BCR) of prostate cancer occurs in 20-30% of the patient before a more definitive diagnosis of metastatic disease can be established by conventional imaging modalities. With a PET-CT, using the radiopharmaceutical tracer [18F]-DCFPyL it is thought to early detect recurrent and/or metastatic prostate cancer in patients with BCR

Two PET/CT scans will be made during the study, one with the radiopharmaceutical study product [18F]-DCFPyL and one with the radiopharmaceutical product [18F]-Fluoromethylcholine.

The general risks related to any PET scan are especially:
- Irradiation risks which are very low. Indeed, the main risk related to irradiation concerns the kidneys which are the critical organs as they will participate in the elimination of the diagnostic product from the body. Therefore, the maximum dose to be injected was chosen so that it will be lower than the irradiation received during an x-ray of the kidneys.
- Allergic reactions that may occur but remain extremely low.

The risk related to the PET scan with [18F]-DCFPyL:
- [18F]-DCFPyL has been used in the US and in the Netherlands in many clinical studies, the product appeared to be well tolerated and no severe side effects were reported in those studies.
- Based on those studies, the patient may experience fatigue, dysgeusia or headache.

The risk related to the PET scan with [18F]-Fluoromethylcholine:
- To date, no side effects have been described.

With a PET scan X-ray radiation and radioactive substances are used. The total radiation burden in this study is 17.2 mSv. In comparison: the background radiation in the Netherlands is ~2.5 mSv, per year.
The radiation used during the study may cause damage to the patient's health.

Blood draw:
The risks involved in drawing blood from a vein may include, but are not limited to, momentary discomfort and/or pain at the site of the blood draw, possible bruising, redness, and swelling around the site, bleeding at the site, feeling of lightheadedness when the blood is drawn, and rarely, an infection at the site of the blood draw.

The following procedures will be performed during the study:
- undergo physical examination (1x)
- measurement of vital signs (6x)

Contacts

Public
Curium PET France

rue Marie Curie 3
Saint-Beauzire 63360
FR
Scientific
Curium PET France

rue Marie Curie 3
Saint-Beauzire 63360
FR

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Male.
2. Age * 18 years.
3. Histopathological proven prostate adenocarcinoma per original diagnosis.
4. First suspected recurrence of prostate cancer based on rising prostate-specific antigen (PSA) after initial curative therapy with radical prostatectomy of PSA * 0.2 ng/mL confirmed by a subsequent PSA value of *0.2 ng/mL or with radiation therapy (external beam or brachytherapy) of PSA > 2

ng/mL above the nadir after therapy regardless of the serum concentration of the nadir.
5. Able and willing to provide informed consent and comply with protocol requirements
6. Patient who can undergo all study procedures per Investigator*s point of view
7. Patient with social insurance cover.

Exclusion criteria

1. ECOG > 2
2. History of previous salvage therapies (including salvage radiotherapy or salvage lymph node dissection)
3. History of adjuvant radiotherapy
4. History of cryotherapy, high-intensity focused ultrasound (HIFU)
5. Other active malignant tumour
6. Treatment with Androgen Deprivation Therapy (ADT) in the past 30 days or ongoing
7. Treatment with colchicine in the past 8 days or ongoing
8. Treatment with hematopoietic colony stimulating factors (CSF) in the past 5 days or ongoing
9. Unable to lie supine for imaging
10. Known allergy to investigational or reference products or to any excipients
11. Unable to provide written consent (linguistic or psychological inability)
12. Participation in another clinical study within one month prior to inclusion
13. Uncooperative, in the Investigator's opinion.
14. Subjects deprived of their freedom by administrative or legal decision or who are under guardianship

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-10-2020
Enrollment:	30
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	18F-DCFPyL
Generic name:	18F-DCFPyL
Product type:	Medicine
Brand name:	Fluorocholine (18F) Cis bio international
Generic name:	Fluorocholine (18F) Chloride
Product type:	Medicine
Brand name:	PROSTATEP 500 MBq/mL
Generic name:	Fluorocholine (18F)

Ethics review

Approved WMO Date:	09-04-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-06-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-08-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-09-2020

Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-10-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-11-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-04-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-06-2021
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	EUCTR2020-000121-37-NL
CCMO	NL72802.029.20