18F-fluciclovine PET/CT and 18F-DCFPyL PET/CT in patients with biochemical recurrence of disease after radical prostatectomy: a prospective, single-centre, single-arm, comparative imaging trial.

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To head-to-head compare the per patient detection rate of 18F-Fluciclovine PET/CT versus 18F-DCFPyL PET/CT in patients with BCR of disease after radical prostatectomy.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Prostatic disorders (excl infections and inflammations)
Study type	Interventional

Summary

ID

NL-OMON50844

Source
ToetsingOnline

Brief title
RENARD trial

Condition

- Prostatic disorders (excl infections and inflammations)

Synonym
malignancy of the prostate, Prostate cancer

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Curium PET France

Intervention

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

Outcome measures

Primary outcome

The *per patient detection rate* (proportion of patients with PET-positive findings) of 18F-fluciclovine versus 18F-DCFPyL PET/low-dose CT for the identification of tumor/ metastatic localization(s).

Secondary outcome

1. the detection rates on a *per patient-based* analysis of 18F-DCFPyL and 18F-fluciclovine PET/low-dose CT, stratified by PSA level (0.2-0.5; 0.51-1.0; 1.01-2.0 ng/mL);

2. the per-region detection rate of 18F-fluciclovine versus 18F-DCFPyL;

3. the side-effects of 18F-DCFPyL;

4. the inter-observer agreement.

Study description

Background summary

Prostate cancer (PCa) has the highest incidence of all cancers among men of 50 years and older in the Western world. The most common treatments for men with localized disease are radical prostatectomy and local radiation therapy. After radical prostatectomy or radiation therapy, between 27% and 53% of patients develop biochemical recurrence (BCR) of disease on follow-up. Accurate staging of BCR is important in order to determine prognosis, and select and plan potentially curative salvage treatment. Conventional imaging techniques, such

as bone scintigraphy, and computer tomography (CT), have only limited sensitivity and specificity in the detection of (early) recurrent disease or metastases, and are outperformed by modern imaging modalities (e.g., positron emission tomography/ computed tomography (PET/CT). As of today, 18F-fluciclovine PET/CT (Axumin®) is one of the two registered PET tracers to be used in patients with BCR, besides choline. 18F-fluciclovine PET/CT has slightly better accuracy for the detection of disease recurrence compared to 11C-choline PET/CT (38% versus 32%).

Modern imaging techniques are now being applied and investigated, specifically 18F-PSMA DCFPyL (PSMA PET/CT). 18F-DCFPyL is frequently used for the primary staging of patients with newly diagnosed PCa and for secondary staging purposes in patients with recurrent disease. Current literature suggests that 18F-DCFPyL PET/CT has promising accuracy for localization of disease on BCR, though 18F-DCFPyL PET/CT has not been directly compared to 18F-fluciclovine PET/CT.

Study objective

To head-to-head compare the per patient detection rate of 18F-Fluciclovine PET/CT versus 18F-DCFPyL PET/CT in patients with BCR of disease after radical prostatectomy.

Study design

A prospective, single-center, open-label study. Total population of patients for this study will be 50.

Intervention

All participants of this study will undergo an 18F-fluciclovine PET/low-dose CT and an 18F-DCFPyL PET/low-dose CT. Tracers need to be administered at minimal 24 hours and maximal 15 days from each other.

Study burden and risks

1. The study will require time and effort from participating patients.
2. One additional site visit to the nuclear department facility is necessary, to perform both scans.
3. Patients will undergo one additional PET/low-dose CT scan, resulting in an extra radiation dose of approximately 8mSv. The burden of such a low additional radiological exposure dose is probably negligible with respect to cancer genesis (estimated risk 0.0267% in a 65-year-old male).
4. No questionnaires will be delivered.
5. No physical examinations or other tests will be performed.
6. Adverse events observed, mentioned upon open questioning, or spontaneously reported will be recorded during the first 24 hours following each injection

for the investigational imaging tracer.

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

*Male.
*Age >= 18 years.
*Histopathological confirmed prostate adenocarcinoma per original diagnosis.
*History of RARP.
*Biochemical recurrence of prostate cancer based on two consecutive measurable PSA levels of 0.2 -2.0 ng/mL.
*Ability to understand and sign the written informed consent form.
*Patients who can undergo all study procedures per investigator*s point of

view.

Exclusion criteria

*Another active malignant tumor, except skin basal cell carcinoma.
*pN1 disease after ePLND.
*Any change in prostate cancer treatment between both PET/CT scans.
*History of previous salvage therapies (including salvage radiotherapy or salvage lymph node dissection).
*History of salvage radiotherapy of the prostate bed.
*History of cryotherapy, high-intensity focused ultrasound (HIFU).
*Treatment with androgen deprivation therapy (ADT) in the past 30 days or ongoing.
*Unable to lie supine or still for imaging.
*Known allergy to investigational or reference products or to any excipients.
*Unable to provide written consent (linguistic or psychological inability).
*Uncooperative, in the Investigator*s opinion.

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-01-2022
Enrollment:	50
Type:	Actual

Medical products/devices used

Product type:	Medicine

Brand name:	18F-DCFPyL
Generic name:	18F-DCFPyL
Product type:	Medicine
Brand name:	Axumin
Generic name:	18F-fluciclovine

Ethics review

Approved WMO Date:	22-04-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-09-2021
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
EudraCT	EUCTR2021-001123-40-NL
CCMO	NL77045.029.21