F18-PSMA-1007 PET for early biochemical recurrence of prostate cancer, comparison with 18F-Fluciclovine.

Published: 11-06-2018 Last updated: 11-04-2024

Main objective is to compare detection efficacy of 18F-PSMA-1007 PET-CT to 18F-Fluciclovine, in patients with early biochemical recurrence of prostate cancer.

Ethical review Approved WMO **Status** Recruitment stopped

Health condition type Reproductive neoplasms male malignant and unspecified

Study type Interventional

Summary

ID

NL-OMON48761

Source

ToetsingOnline

Brief title

F18-PSMA-1007 PET for early biochemical recurrence of prostate cancer.

Condition

Reproductive neoplasms male malignant and unspecified

Synonym

Prostate carcinoma; adenocarcinoma of the prostate

Research involving

Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: ABX advanced biochemical

compounds, Bedrijven

Intervention

Keyword: [18F]F-PSMA-1007, biochemical recurrence, prostate cancer

Outcome measures

Primary outcome

Main study parameter: detection efficacy of the different PET-tracers. Both the number of patients in which disease activity is objected as well as the number of prostate cancer lesions that are detected will be compared. Goal is to show superiority of 18F-PSMA-1007 compared to 18F-Fluciclovine.

Secondary outcome

Secondary study parameters:

- Comparing specificity, where the golden standard is consensus by the expert panel using all available information including 6 months follow up data.
- Analysis of the sensitivity per area: local recurrence, locoregional lymph nodes, distant lymph nodes, bone metastases, extraskeletal organ metastases

Study description

Background summary

18F-PSMA-1007 is a new radiopharmaceutical for detection of prostate cancer with potential benefits over 18F-Fluciclovine, such as higher detection rates in low PSMA levels and small lesions, lower bone marrow uptake and higher tumour-background ratio. Therefore, 18F-PSMA-1007 PET may be more sensitive in detecting local recurrence and metastases of prostate cancer.

Study objective

Main objective is to compare detection efficacy of 18F-PSMA-1007 PET-CT to 18F-Fluciclovine, in patients with early biochemical recurrence of prostate cancer.

Study design

Comparative phase II diagnostic study.

Intervention

50 male patiënts will receive a 18F-PSMA-1007 PET-CT (90 minutes post injection) and a 18F-Fluciclovine PET-CT (<15 minutes after injection). Injected dose of the 18F-PSMA-1007 will be 4 MBq/kg \pm 10% 18F-PSMA-1007. The injected dose of 18F-Fluciclovine is 370 MBq \pm 10% MBq.

Study burden and risks

Patients undergo two PET-CT*s. The radiopharmaceuticals are administered intravenously. The time-investment is approximately 3 hours for the 18F-PSMA-1007 PET and 1 hours for the 18F-Fluciclovine PET-CT. The radiation dose of both PET-CT*s together is approximately 20-25 mSv. No detrimental effects are expected from this radiation dose. A clinical report will be made of both scans. The (expected) superiority of 18F-PSMA-PET over 18F-Fluciclovine will probably be most clearly visualised in small lesions, therefore patients with early biochemical recurrence will be selected.

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

- Males * 18 years
- Histologically proven adenocarcinoma of the prostate
- Prior local treatment with curative intent
- Biochemical recurrence with (rising) PSA-levels of 0.2-5.0 ug/L
- PSA level determined <8 weeks before study participation

Exclusion criteria

- Contra-indications for PET-CT: claustrophobia or inability to lay still for the duration of the exam
- Other cancer < 2 years prior to biochemical recurrence

Study design

Design

Study phase: 2

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruitment stopped

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Start date (anticipated): 30-01-2020

Enrollment: 50

Type: Actual

Medical products/devices used

Product type: Medicine

Brand name: [18F]F-fluciclovine

Generic name: Axumin

Product type: Medicine

Brand name: [18F]F-PSMA-1007

Generic name: [18F]F-PSMA-1007

Ethics review

Approved WMO

Date: 11-06-2018

Application type: First submission

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date: 25-03-2019

Application type: Amendment

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date: 10-10-2019

Application type: First submission

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date: 27-11-2019

Application type: Amendment

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date: 28-11-2019

Application type: Amendment

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

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 EUCTR2018-001267-22-NL

CCMO NL65593.091.18