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

Published: 11-06-2018
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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 ±10% 18F-PSMA-1007. The injected dose of 18F-Fluciclovine is 370 MBq ± 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

Public
Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 10
Nijmegen 6525 GA
NL
Scientific
Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 10
Nijmegen 6525 GA
NL

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

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