The diagnostic value of FAPI PET/CT in staging of newly diagnosed PCa

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Ethical review	Approved WMO
Status	Pending
Health condition type	Reproductive neoplasms male malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON53628

Source
ToetsingOnline

Brief title
proFAPI

Condition

- Reproductive neoplasms male malignant and unspecified

Synonym
Prostate cancer

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Cyclotron Noordwest BV,Eigen afdeling

Intervention

Keyword: Diagnostic value, FAPI PET/CT, Prostate cancer, PSMA PET/CT

Outcome measures

Primary outcome

The added diagnostic value of FAPI PET/CT, relative to PSMA PET/CT, in staging of newly diagnosed PCa.

Secondary outcome

Secondary endpoints: the diagnostic accuracy of FAPI PET/CT by correlating FAPI PET/CT findings to clinical follow-up and histopathological and/or laboratory findings.

Study description

Background summary

One in seven men will be affected by prostate cancer. When diagnosed with prostate cancer, in some cases it is important to assess the extent of the disease. A PSMA PET/CT scan is used for this. A PSMA PET/CT scan works by administering a radioactive contrast agent. It enters the bloodstream through a drip and spreads throughout the body. The radioactive contrast agent emits radiation for a short time. This radiation can be converted into images during the scan. On these images, cancerous tissue lights up many times more than healthy tissue. The accuracy of this current technique to detect possible metastases of prostate cancer is good, but in some cases not optimal.

To improve accuracy, we are researching a new radioactive contrast agent, 18F-FAPI-74. 18F-FAPI-74 consists of very small radioactive particles that can be taken up by cancer tissue. This contrast agent differs from the contrast agents currently used in that it targets the cells surrounding the prostate cancer cells and not the prostate cancer cells themselves. 18F-FAPI-74 has already been studied in various cancers (breast cancer, skin cancer, colon cancer, lung cancer, etc.) with good results. The accuracy of 18F-FAPI-74 in these cancers is as good and sometimes even better than current radioactive contrast agents. These studies have shown that 18F-FAPI-74 can be used safely and does not cause any complaints. However, to date, few studies have

investigated the use of 18F-FAPI-74 in men with newly diagnosed prostate cancer. In this study we therefore want to investigate whether 18F-FAPI-74 is better than current techniques in detecting prostate cancer metastases in men with recently diagnosed prostate cancer.

Study objective

Demonstrating or ruling out metastasis of prostate cancer is necessary to draw up a good treatment plan and helps to estimate the course of the disease. The aim of this study is to find out whether use of the radioactive contrast agent 18F-FAPI-74 can improve the accuracy of detecting prostate cancer metastases compared to a standard contrast agent currently used (18F-PSMA-JK7).

Study design

This is an investigator initiated, multicenter, prospective, non-randomized diagnostic pilot study and follows a prospective cross-sectional design.

Study burden and risks

Participation in this study has no significant risks and will not induce a delay in diagnosis or treatment since outcomes of FAPI PET/CT scans will not guide treatment decisions. The FAPI PET/CT scan involves a total procedure duration of 1.5 hour and an estimated radiation dose of 6 mSv per procedure (3 mSv for an average administered dosage of 200 MBq 18F-FAPI-74, and 3 mSv for the associated low dose CT scan). This radiation dose of 6 mSv is well within the range of normal diagnostic procedures and does not induce a significant risk in the selected population with PCa. In addition, the 18F-FAPI-74 radiopharmaceutical is thus far not associated with side effects after injection. Finally, it may be anticipated that the value of an improved and more sensitive image modality could have an improved impact on the cancer treatment.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Male, aged >= 18 years;
- WHO performance status 0, 1 or 2;
- Written informed consent;
- Biopsy-proven newly diagnosed PCa;
- International Society of Urological Pathology (ISUP) grade group (GG) >= 3 and/or PSA >= 20 ng/ml and/or >=cT3a.
If all of the criteria above are met, a subject must also meet all of the following subgroup specific criteria:

Group 1 (n=15):
- PSMA PET/CT with PSMA-avid primary tumor with PSMA-avid loco-regional and/or distant metastases.

Group 2 (n=15):
- PSMA PET/CT with PSMA-avid primary tumor with no PSMA-avid loco-regional or distant metastases;
- Increased risk of nodal metastases according to the Briganti 2019 nomogram (Briganti >=40%)
- Scheduled for (laparoscopic) prostatectomy including ePLND.

Exclusion criteria

- Known second malignant disease that may complicate image interpretation.
- Inability to cooperate with the scan process: inability to lie relatively still and in supine for 30-60 minutes or patient body habitus above scanner dimensions.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2023
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Date:	17-10-2023
Application type:	First submission
Review commission:	METC NedMec

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
CCMO	NL83218.041.23