

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The preliminary evaluation of therapeutic efficacy of 225Ac-PSMA-617 in patients of metastatic castrate resistant prostate cancer

Protocol summary

Study aim

The primary objective is to conduct an initial evaluation of the efficacy of therapeutic radiopharmaceutical 225Ac-PSMA in treating treatment-resistant prostate cancer.

Design

The study is a primary study and does not have a control group. The sample size will be ten patients, and it is possible that patients may receive multiple treatment cycles.

Settings and conduct

The study did not involve a placebo. The administration of the radiopharmaceutical will take place in the nuclear medicine department of Hashemi Nejad Hospital. Patients will be admitted to the department on the day of treatment and, after receiving necessary explanations and signing an informed consent form, will receive the radiopharmaceutical through intravenous injection.

Participants/Inclusion and exclusion criteria

The patients with a diagnosis of metastatic prostate cancer and adequate kidney, liver, and bone marrow function will be enrolled in the study. The entry of patients whose PET/CT or SPECT/CT imaging shows a lower radiopharmaceutical uptake than their liver uptake will be avoided.

Intervention groups

The study does not define a control group, and patients who do not have standard treatment at this stage will be enrolled and will receive the therapeutic radiopharmaceutical 225Ac-PSMA-617.

Main outcome variables

Measurement of PSA level, assessment of pain in patients using standard questionnaires

General information

Reason for update

Acronym

AcPC

IRCT registration information

IRCT registration number: **IRCT20211206053304N2**

Registration date: **2024-02-27, 1402/12/08**

Registration timing: **registered_while_recruiting**

Last update: **2024-02-27, 1402/12/08**

Update count: **0**

Registration date

2024-02-27, 1402/12/08

Registrant information

Name

Leila Hassanzadeh

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-17, 1402/11/28

Expected recruitment end date

2025-02-16, 1403/11/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The preliminary evaluation of therapeutic efficacy of 225Ac-PSMA-617 in patients of metastatic castrate resistant prostate cancer

Public title

The efficacy assessment of 225Ac-PSMA-617 in Prostate cancer treatment.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Castration-resistant metastatic adenocarcinoma of the prostate should be confirmed by histopathology tests at the time of initial diagnosis. If a patient is in the metastatic stage of prostate cancer mCRPC and has cancerous lesions in distant areas, the primary site of the disease is present. Cancerous lesions in imaging studies with 68Ga-PSMA-11 or 99mTc-PSMA-11 may demonstrate a higher uptake of the radiopharmaceutical than the uptake in normal liver tissue over the course of 4 weeks before treatment. The patient may have previously received second-generation androgen deprivation therapies (Enzalutamide, Abiraterone), or it may not have been possible for the patient to receive them. The patient may have received taxane-based treatments, or it may not have been appropriate to treat them with taxanes. The patient has been treated with the beta-emitting radiopharmaceutical 177Lu-PSMA-617. Eastern Cooperative Oncology Group (ECOG) performance status of less than or equal to 2. Patients' GFR should be above 30

Exclusion criteria:

Low bone marrow function :Hemoglobin concentration of <9 g/dL, platelet count of $<100 \times 10^9/L$, or white blood cell count of $<2.0 \times 10^9/L$, $ANS < 1.0 \times 10^9/L$ Low Kidney function: glomerular filtration rate of less than 30 mL/min/1.73 m² of body surface area; Serum/plasma creatinine $\geq 1.5 \times ULN$ or creatinine clearance < 50 mL/min based on Cockcroft-Gault formula Low Liver function is defined (Albumin less than 2.5 g/dL, Billirubin $\geq 3 \times ULN$, γ -Alanine aminotransferase (ALT) or aspartate aminotransferase (SAT) $\geq 3.0 \times ULN$. Patients who do not have cancer lesions that absorb radioactivity in PET or SPECT imaging Patients whose histology from the sampled tissue indicates sarcomatous/spindle cell/small cell differentiation. Untreated patients with kidney obstruction Patients with active secondary malignancy Patients with Chronic or acute glomerulonephritis Patients who have received chemotherapy, wide-field radiotherapy, and radiopharmaceuticals in the last 8 weeks are excluded from the study.

Age

No age limit

Gender

Male

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: 10

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

School of medicine, IRAN University of Medical Sciences

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Hemmat Highway, next to Milad Tower, Iran University of Medical Sciences

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Approval date

2023-11-20, 1402/08/29

Ethics committee reference number

IR.IUMS.FMD.REC.1402.350

Health conditions studied**1****Description of health condition studied**

metastatic castration-resistant Prostate Cancer (CRPC)

ICD-10 code

C61

ICD-10 code description

Malignant neoplasm of prostate

Primary outcomes**1****Description**

PSA level measurement

Timepoint

Before treatment and every four weeks after receiving the radiopharmaceutical

Method of measurement

Blood Test

Secondary outcomes

empty

Intervention groups

1

Description

The treatment method in this study involves the use of therapeutic radiopharmaceutical Alpha-225Ac-PSMA. Patients with treatment-resistant prostate cancer receive the radiopharmaceutical therapy on the treatment day in the nuclear medicine department. The radiopharmaceutical provided by the manufacturer (Pars Isotope) is administered intravenously after hydrating the patient with approximately one liter of normal saline. The treatment starts with an activity of 100 kBq/kg based on the patient's weight, repeated every 8 weeks for three cycles or until evidence of disease progression, unacceptable toxicity, or patient refusal to continue the treatment, whichever comes first.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hashemineghad Hospital

Full name of responsible person

Dr. Leila Hassanzadeh

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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Leila Hassanzadeh

Position

Assistant Professor

Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable