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 <۹ g/dL,platelet count of <۱۰۰ × ۱۰۹/L, orwhite blood cell count of <۲.۰ × ۱۰۹/L), ANS<۱.۵×۱۰۹/ Low Kidney function: glomerular filtration rate of less than 30 mL/min/1.73 m۲ of body surface area;Serum/plasma creatinine˃1.5×ULN or creatinin clearance<50 ml/min based on cockcroft-Gault formula Low Liver function is defined(Albumin less than 2.5 g/dL, Billirubin˃3×ULN و یا˗Alanine aminotransferase (ALT) or aspartate aminotransferase (SAT)˃3.۰×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
Street address
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

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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
Ph.D.

Other areas of specialty/work
Nuclear Medicine

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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