Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Targeted α-Therapy in Metastatic Castration Resistant Prostate Cancer with 225Ac-PSMA-617

Protocol summary

Study aim

The efficiency of endoradiotherapy with 225Ac-PSMA in metastatic castration-resistant prostate cancer patients (mCRPC)

Design

This is an interventional clinical trial with a single group design of 10 patients, performing between November 2021 and November 2022 that will be followed between treatment sessions.

Settings and conduct

Patients are selected and justified in the nuclear medicine center of the Persian Gulf hospital at Bushehr. The consent form is obtained and finally, the treatment will be performed with intravenous injection of 225-Ac-PSMA-617. After injection, patients will be undergone a whole-body scan for the assessment of radiotracer distribution. Six to eight weeks after the 225-Ac-PSMA-617 therapy, the patients will be visited by oncologists and nuclear medicine physicians and if there was not any toxicity, the next treatment session will be performed.

Participants/Inclusion and exclusion criteria

Patients must have had progressive metastatic castration-resistant prostate cancer, positive 68Ga-PSMA-11 PET/CT scan, recovered or stabilized to ≤ Grade 2 from all clinically significant toxicities related to prior prostate cancer therapy, and an ECOG performance status of 0 to 2. Exclusion criteria: Previous treatment with Strontium-89, Samarium-153, Rhenium-186, Rhenium-188, Radium-223 or Hemi-body irradiation or previous PSMA-targeted radioligand therapy, patients diagnosed with other malignancies that are expected to alter life expectancy or may interfere with disease assessment.

Intervention groups

We are going to use a single group of patients to evaluate the efficiency of 225-Ac-PSMA-617 in the treatment of prostate cancer.

Main outcome variables

The proportion of patients who have a partial, stable (not-progressed), or complete response to therapy.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210612051548N1**
Registration date: **2021-09-22, 1400/06/31**
Registration timing: **prospective**

Last update: **2021-09-22, 1400/06/31**
Update count: **0**

Registration date

2021-09-22, 1400/06/31

Registrant information

Name

Majid Assadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 77 3332 0361

Email address

assadipoya@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Targeted α-Therapy in Metastatic Castration Resistant Prostate Cancer with 225Ac-PSMA-617

Public title
Targeted α-Therapy in Prostate Cancer

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients must have had progressive metastatic castration-resistant prostate cancer. Patients must have a positive 68Ga-PSMA-11 PET/CT scan. Patients must have recovered or stabilized to ≤ Grade 2 from all clinically significant toxicities related to prior prostate cancer therapy. Patients must have an ECOG performance status of 0 to 2.

Exclusion criteria:
Previous treatment with Strontium-89, Samarium-153, Rhenium-186, Rhenium-188, Radium-223 or hemi-body irradiation or previous PSMA-targeted radioligand therapy. The patient was diagnosed with other malignancies that are expected to alter life expectancy or may interfere with disease assessment (Patients with a prior history of malignancy who have been disease-free for more than 3 years are eligible).

Age
From **18 years** old

Gender
Male

Phase
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
Research ethics committee of Bushehr university of medical sciences

Street address
Bushehr University of Medical Sciences, Bushehr,Iran

City
Bushehr

Province
Boushehr

Postal code
45654775

Approval date
2021-06-27, 1400/04/06

Ethics committee reference number
IR.BPUMS.REC.1400.057

Health conditions studied

1

Description of health condition studied
Prostate cancer

ICD-10 code
C61

ICD-10 code description
Malignant neoplasm of prostate

Primary outcomes

1

Description
Numbe of treated prostate cancer patients

Timepoint
4-6 weeks after last treatment session

Method of measurement
Image-based response using 68Ga-PSMA PET/CT

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this study, the 225Ac-PSMA-617 radiopharmaceutical is injected intravenously into 10 patients with prostate cancers according to the 68Ga-PSMA-11 PET/CT. Then whole-body scan is performed at 24 hours, and 48 hours after injection to assess radiotracer distribution. Six to eight weeks after the 225-Ac-PSMA-617 therapy, the patients will be visited by oncologists and nuclear medicine physicians and if there was not any toxicity, the next treatment session will be performed.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Nuclear Medicine Center, Persian Gulf Hospital

Full name of responsible person
Majid Assadi

Street address
Persian Gulf Hospital,Taleghani Street,Bushehr,Iran

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Bushehr

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Boushehr University of Medical Sciences

Full name of responsible person
Gholamreza Khamisipour

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Vice-Chancellor for Research and Technology of Bushehr University of Medical Sciences, Salman-e-Farsi Blvd,Bushehr,Iran.

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Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Bushehr 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
Boushehr University of Medical Sciences

Full name of responsible person
Majid Assadi

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
Nuclear Medicine

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Person responsible for updating data

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Research Instructor

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https://pgnmrc.bpums.ac.ir/fa/index.aspx

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
Yes - There is a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

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

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
There is no further information

When the data will become available and for how long
There is no further information

To whom data/document is available
There is no further information

Under which criteria data/document could be used
There is no further information

From where data/document is obtainable
There is no further information

What processes are involved for a request to access data/document
There is no further information

Comments