

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Efficacy and safety of Lutetium-177-PSMA-617 therapy in patients with metastatic prostate cancer after radical prostatectomy and bilateral orchiectomy

Protocol summary

Study aim

Determining the efficacy and safety of Lutetium-177-PSMA-617 therapy in patients with metastatic prostate cancer after radical prostatectomy and bilateral orchiectomy

Design

Clinical trial without control group, phase 2, on patients with metastatic prostate cancer after radical prostatectomy and bilateral orchiectomy

Settings and conduct

Patients with metastatic prostate cancer after radical prostatectomy and bilateral orchiectomy who met the eligibility criteria are recommended to receive Lutetium therapy. After obtaining the written informed consent, and a complete clinical history a fasting serum sample will be taken to perform hematological and biochemical tests and an ultrasound of the urinary tract will be performed. And DTPA SCAN is done. Patients receive two courses of Lutetium therapy, they are evaluated every 4 weeks in terms of treatment complications, liver function parameters and cell counts. They are followed up by blood. PSA is measured every month and a whole body scan is performed 24 hours after injection. Response to treatment will be assessed after 2 and 4 months of Lutetium therapy in terms of PSA, AIP serum levels, improvement of clinical symptoms (such as bone pain), and reduction of bone and lymph metastatic areas using 68Ga-PSMA PET/CT scan.

Participants/inclusion and exclusion criteria

1-Men with metastatic prostate cancer after radical prostatectomy and bilateral orchiectomy 2- 68Ga-PSMA-PET/CT positive scan Exclusion criteria: 1- Creatinine ≥ 2 mg/dl 2-Obstructive DTPA SCAN 3-GFR ≤ 30 4-WBC ≤ 20000 5-PLAT ≤ 75000 6-ECOG > 2 7- Patients with life expectancy < 12 weeks

Intervention groups

Patients with metastatic prostate cancer who

Lutetium-177-PSMA-617 as a treatment (2 courses with 2 months interval). Not have control group.

Main outcome variables

PSA; ALT; AST; ALKP; LDH; WBC; Hb; Plt; Creatinin; BUN; GFR; ECOG; bone and lymph metastatic areas; Gleason score

General information

Reason for update

Acronym

-

IRCT registration information

IRCT registration number: **IRCT20230414057906N1**

Registration date: **2023-04-23, 1402/02/03**

Registration timing: **prospective**

Last update: **2023-04-23, 1402/02/03**

Update count: **0**

Registration date

2023-04-23, 1402/02/03

Registrant information

Name

Saber Amanollahi Soudmand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2207 3035

Email address

saberas_2008@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-05, 1402/02/15

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy and safety of Lutetium-177-PSMA-617 therapy in patients with metastatic prostate cancer after radical prostatectomy and bilateral orchiectomy

Public title

Efficacy and safety of Lutetium-177-PSMA-617 therapy in patients with metastatic prostate cancer after radical prostatectomy and bilateral orchiectomy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Men with metastatic prostate cancer after radical prostatectomy and bilateral orchiectomy 68Ga-PSMA-PET/CT positive scan Having willingness to participate in this study

Exclusion criteria:

Creatinine ≥ 2 mg/dl Obstructive DTPA SCAN $GFR \leq 30$ $WBC \leq 2000$ $Hb \leq 8$ g/dl Previous history of chemotherapy/radiotherapy for prostate cancer $PLAT \leq 75000$ $ALT/AST > 5$ times of upper normal limit for those with liver metastasis or < 2 times for those without liver metastasis. Patients with life expectancy < 12 weeks

Age

From **20 years** old to **85 years** old

Gender

Male

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **12**

Randomization (investigator's opinion)

N/A

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features

Pilot study

Secondary Ids

empty

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

Ethics Committee in Research Faculty of Medicine, Shahid Beheshti University of Medical Sciences

Street address

Velenjak Street- Daneshjoo Bolvard- Koodakyar Allay

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2022-05-10, 1401/02/20

Ethics committee reference number

IR.SBMU.MSP.REC.1401.092

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**

(prostate specific antigen)PSA

Timepoint

Before study, 2 and 4 months after Lutetium

Method of measurement

Blood test

2**Description**

Bone pain Score

Timepoint

Before study, 2 and 4 months after Lutetium

Method of measurement

Visual Analog Scale

3**Description**

Alkaline phosphatase

Timepoint

Before study, 2 and 4 months after Lutetium

Method of measurement

Blood test

4

Description

White blood cells

Timepoint

Before study, 2 and 4 months after Lutetium

Method of measurement

Blood test

5

Description

Hemoglobin

Timepoint

Before study, 2 and 4 months after Lutetium

Method of measurement

Blood test

6

Description

platelet count test

Timepoint

Before study, 2 and 4 months after Lutetium

Method of measurement

Blood test

7

Description

Blood urea nitrogen

Timepoint

Before study, 2 and 4 months after Lutetium

Method of measurement

Blood test

8

Description

Creatinine

Timepoint

Before study, 2 and 4 months after Lutetium

Method of measurement

Blood test

9

Description

Aspartate aminotransferase

Timepoint

Before study, 2 and 4 months after Lutetium

Method of measurement

Blood test

10

Description

Alanine transaminase

Timepoint

Before study, 2 and 4 months after Lutetium

Method of measurement

Blood test

11

Description

Lactate dehydrogenase

Timepoint

Before study, 2 and 4 months after Lutetium

Method of measurement

Blood test

Secondary outcomes

empty

Intervention groups

1

Description

At first, PSMA-617 is labeled with LU-177 chloride. LU-PSMA is infused at the rate of -7.4GBq within 30-60 seconds along with one liter of normal saline serum. All the standard measures of lutetium therapy include placing an ice pack on the salivary glands from 30 minutes before to 4 hours after and consuming plenty of fluids before and after the treatment. The patient is monitored 4 hours after the injection and then discharged.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Labbafinezhad Hospital

Full name of responsible person

Saber Amanollahi Soudmand

Street address

Labbafinezhad Hospital, 9th Bostan, Pasdaran Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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Kodakyar Allay, Daneshjoo Bolvard, Velenjak Street

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Saber Amanollahi Soudmand

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries

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Person responsible for updating data

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information.

Study Protocol

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

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

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

Data Dictionary

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

Title and more details about the data/document

All data is potentially shareable after de-identifying individuals.

When the data will become available and for how long

The access period starts 6 months after the results are

published.

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Using data for running a meta-analysis

From where data/document is obtainable

Principle investigator

What processes are involved for a request to access data/document

Submission and approval in the research committee (on average 2 months)

Comments