Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

Efficacy and safetyof Lutetim-177-PSMA-617 therapy in paitents with metastatic prostate cancer after radical prostatectomyand bilateral orchitectomy

Protocol summary

Study aim

Determining the efficacy and safety of Lutetim-177-PSMA-617 therapy in paitents with metastatic prostate cancer after radical prostatectomyand bilateral orchitectomy

Design

Clinical trial without control group, phase 2, on patients with metastatic prostate cancer after radical prostatectomyand bilateral orchitectomy

Settings and conduct

Patients with metastatic prostate cancer after radical prostatectomyand bilateral orchitectomy who met the eligibility criteria are recommended to receive Lutetim therapy. After obtaining the written inform 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 course 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, AlP 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 prostatectomyand bilateral orchitectomy 2- 68Ga-PSMA-PET/CT positive scan Exclusion criteria: 1- Creatinine >=2mg/dl 2-Obstructive DTPA SCAN 3-GFR≤30 4-WBC≤2000l 5-PLAT≤75000 6-ECOG>2 7- Patients with life expectancy<12 weeks

Intervention groups

Patients with metastatic prostate cancer who Lutetim-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 safetyof Lutetim-177-PSMA-617 therapy in paitents with metastatic prostate cancer after radical prostatectomyand bilateral orchitectomy

Public title
Efficacy and safety of Lutetim-177-PSMA-617 therapy in paitents with metastatic prostate cancer after radical prostatectomyand bilateral orchitectomy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Men with metastatic prostate cancer after radical prostatectomy and bilateral orchitectomy 68Ga-PSMA-PET/CT positive scan Having willingness to participate in this study
Exclusion criteria:
Creatinine >=2 mg/dl Obstructive DTPA SCAN GFR≤30 WBC≤2000 Hb≤8g/dl Previous history of chemotherapy/radiotherapy for prostate cancer PLAT≤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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Tehran
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1666663111
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saberas_2008@yahoo.com

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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site@sbmus.ac.ir

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

Contact

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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 mata-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