

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Treatment of castration-resistant metastatic prostate cancer, refractory to routine treatment with Lu177-PSMA

Protocol summary

2018-03-14, 1396/12/23

Study aim

Evaluation of efficacy and complication of peptide receptor radionuclide therapy (PRRT) with Lu177-PSMA in patients with Castration-resistant prostate cancer (CRPC)

Design

20 patients with prostate cancer (pathological report) and refractory to routine treatment (CRPC) referred by an oncologist and imaged by Ga68-PSMA PET/CT if they had uptake in metastases, they enrolled in the study

Settings and conduct

If metastases showed uptake in PSMA -PET/CT scan then the patients admitted by nuclear medicine department in ghaem hospital of Mashad University of medical sciences for slow infusion of Lu177-PSMA

Participants/Inclusion and exclusion criteria

Castration-resistant prostate cancer patients with metastases and refractory to routine treatment.
Exclusion criteria: Renal failure and life expectancy less than 4 months

Intervention groups

Efficacy of treatment and complication of Lu-PSMA in CRPC patients

Main outcome variables

PSA level, free progression survival, pain relief change, quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180113038331N1**
Registration date: **2018-03-14, 1396/12/23**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-14, 1396/12/23**

Update count: **0**

Registration date

Registrant information

Name

Kamran Aryana

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3881 3554

Email address

aryanak@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-13, 1396/09/22

Expected recruitment end date

2018-12-13, 1397/09/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Treatment of castration-resistant metastatic prostate cancer, refractory to routine treatment with Lu177-PSMA

Public title

Treatment of patients with castration-resistant metastatic prostate cancer with nuclear medicine procedure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with Hx of metastatic prostate cancer resistant to usual treatment Positive Ga68-PSMA PET/CT scan

ESOG 0-2

Exclusion criteria:

survival less than 4 months GFR less than 40cc/min
Serum creatinin >1.5 Urinary tract obstruction Bone
marrow suppression (WBC <2500 Plat<80000 Hct<8

Age

No age limit

Gender

Male

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 20

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

Ethics committee of Mashhad University of Medical
Sciences

Street address

Daneshgah St

City

Mashhad

Province

Razavi Khorasan

Postal code

91839

Approval date

2017-07-05, 1396/04/14

Ethics committee reference number

IR.MUMS.fm.REC.1396.414

Health conditions studied

1

Description of health condition studied

Castration resistant metastatic prostate cancer

ICD-10 code

C61

ICD-10 code description

Malignant neoplasm of prostate

Primary outcomes

1

Description

1-Change the number of metastases

Timepoint

After three cycle of therapy

Method of measurement

1-Comparison with result of first functional and
anatomical imaging

Secondary outcomes

1

Description

Intensity of pain

Timepoint

Before treatment and then every week until to the end of
treatment

Method of measurement

Standard check list

2

Description

Quality of life

Timepoint

Every 15 days

Method of measurement

Karnofsky score

Intervention groups

1

Description

Intervention group: Castration resistant metastatic
prostate cancer . Administration of Lu-PSMA 150-200 mCi
every 2 months for 3 to 5 courses

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Kamran Aryana

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Kamran Aryana
Street address
Ahmadabad st -Ghaem hospital
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Email
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Pars Isotope company
Proportion provided by this source
90
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Kamran Aryana
Position
Assistant professor of nuclear medicine
Latest degree
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Email

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

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

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

A part of information

When the data will become available and for how long

After publication

To whom data/document is available

ALL resercher

Under which criteria data/document could be used

No restriction

From where data/document is obtainable

Kamran Aryana Aryanak@mums.ac.ir

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

3 days

Comments