Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

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
2018-03-14, 1396/12/23

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 commitee 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

Street address
Ahmadabad

City
Mashhad

Province
Razavi Khorasan

Postal code
91766-99199
Phone
+98 51 3881 3554
Email
Aryanak@mums.ac.ir

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
City
Mashhad
Province
Razavi Khorasan
Postal code
91839
Phone
+98 51 3881 3554
Email
Aryanak@mums.ac.ir
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 medeicine
Latest degree
Specialist
Other areas of specialty/work
Nuclear Medicine
Street address
Ahmadabad
City
Mashhad
Province
Razavi Khorasan
Postal code
91766-99199
Phone
+98 51 3881 3554
Email
aryanak@mums.ac.ir

Person responsible for scientific 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
Specialist
Other areas of specialty/work
Nuclear Medicine
Street address
Ahmadabad
City
Mashhad
Province
Razavi Khorasan
Postal code
91766-99199
Phone
+98 51 3881 3554
Email
Aryanak@mums.ac.ir

Person responsible for updating data

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
Specialist
Other areas of specialty/work
Nuclear Medicine
Street address
Ahmadabad
City
Mashhad
Province
Razavi Khorasan
Postal code
91766-99199
Phone
+98 51 3881 3554
Email

Aryanak@mums.ac.ir

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