Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Evaluating the theranostic application of Lu177-PSMA in management of refractory thyroid papillary cancer.

Protocol summary

Study aim
To evaluate the therapeutic effect of Lu177-PSMA in refractory but PSMA-avid papillary thyroid cancer

Design
This is a pilot single arm study with 10 patients that are eligible for this treatment based on the tumor board's opinion and their diagnostic evaluation.

Settings and conduct
Due to the low prevalence of eligible patients, there is only one case group. Patients in Isfahan Sayedshohada Cancer Center and Namazi Hospital in Shiraz, after being evaluatedthat by the tumor board, will undergo a diagnostic method with 68Ga-PSMA PET/CT or alternative imaging (Tc99m-PSMA) to determine their eligibility for the therapy with 177Lu-PSMA-617 will be planned for two to four cycles of 177Lu-PSMA therapy. The interval between each treatment cycle is 6 to 8 weeks based on the related guideline.

Participants/Inclusion and exclusion criteria
Patients with metastatic radio-iodine refractory papillary thyroid cancer with baseline, WBC>3000, Hb>9, platelete .cont>70000, AST and ALT<5*nl limit and Cr<2*nl are limited by a multidisciplinary tumor board. The data collected from these patients will be reviewed, and their eligibility for participating in the study will be evaluated. Patients who refused to participate in the study, life-expectancy of <1 month, a history of other concomittant cancers or other end-stage organ diseases, Patients with baseline, WBC<3000, Hb<9, platelete .cont<70000, AST and ALT>5*nl limit and Cr>2*nl limit, will be excluded from the study.

Intervention groups
All patients that have the criteria for the therapy will be planned for two to four cycles of 177Lu-PSMA therapy according to the level of response and the occurrence of the side effects after the first two cycles.

Main outcome variables
baseline serum thyroglobulin, post therapy thyroglobulin level, baseline PSMA avid lesions, post therapy PSMA-avid lesions

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230803059015N1**
Registration date: **2023-08-14, 1402/05/23**
Registration timing: **prospective**

Last update: **2023-08-14, 1402/05/23**
Update count: **0**

Registration date
2023-08-14, 1402/05/23

Registrant information

Name
Zeinab Amirkhani

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-08-23, 1402/06/01

Expected recruitment end date
2024-11-21, 1403/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluating the theranostic application of Lu177-PSMA in management of refractory thyroid papillary cancer.

Public title
Effectiveness of Lu177-PSMA in treatment of refractory thyroid papillary cancer.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with metastatic radio-iodine refractory papillary thyroid cancer Patients with baseline, WBC>3000, Hb>9, platelete .cont>70000, AST and ALT<5*nl limit and Cr<2*nl limit

Exclusion criteria:
Patients who refused to participate in the study Life-expectancy of <1 month History of other concomittant cancer or other end-stage organ disease Patients with baseline, WBC<3000, Hb<9, platelete .cont<70000, AST and ALT>5*nl limit and Cr>2*nl limit

Age
From **18 years** old

Gender
Both

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
The multidisciplinary tumor board, consisting of a surgeon, an endocrinologist, a radio-oncologist, and a nuclear medicine specialist, will review the data of metastatic radioiodine refractory papillary thyroid cancer (RR-PTC) patients and evaluate their eligibility for participating in the study.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
5th floor, Shiraz University Central Building, Islamic Republic Boulevard

City
Shiraz

Province
Fars

Postal code
84471-71946.

Approval date
2023-02-28, 1401/12/09

Ethics committee reference number
IR.SUMS.REC.1402.077

Health conditions studied

1

Description of health condition studied
radio-iodine refractory papillary thyroid cancer

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
serum thyroglobulin level

Timepoint
Monthly

Method of measurement
Blood sampling

2

Description
PSMA avid lesions

Timepoint
Before and after completing the treatment

Method of measurement
Diagnostic method with ۶۸Ga-PSMA PET/CT or alternative imaging (Tc۹۹m-PSMA)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The multidisciplinary tumor board will decide whether patients were eligible for the treatment with 177Lu-PSMA-617. Patients will be considered eligible if one or more metastases were predominantly PSMA positive on 58Ga-PSMA PET/CT or Tc99m-PSMA SPECT/CT with no evidence of any non-PSMA/ non-iodine avid lesions. 10 Patients that have the criteria for the therapy, will be planned for two to four

cycles of 177Lu-PSMA therapy according to rhe level of response and the occurrence of the side effects after the first two cycles. The administered activity will be between 150-200 GBq per cycle proportional to the number and avidity of PSMA-avid lesions. After the administration of ondansetron (8mg IV) and the application of icepack on salivary glands for 30 minutes, the therapeutic radiotracer will be administered by slow intravenous infusion in the inpatients setting with concomitant IV hydration with 1-2 L normal saline during 1-2 hours. In cases with cerebral or spinal metastasis and those with high metastatic volume, dexamethasone ʌmg will be administered daily from one day before the therapy to two days. The interval between each treatment cycle is 6 to 8 weeks based on the related guideline for use of Lu177-PSMA in the other metastatic cancers. During this period, CBc and renal function test will be evaluated every two weeks and will be recorded for the evaluation of any possible toxicity. The patients will be studied for at least 8 months after the therapy for the evaluation of their response to the therapy.

Category

Treatment - Drugs

2

Description

10 patients with radio-iodine refractory papillary thyroid cancer with other options of treatment like tyrosine kinase inhibitors and variables will compare in two groups

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Nuclear Medicine Department of Namazi Hospital in Shiraz

Full name of responsible person

Tahere Qaediyan

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2

Recruitment center

Name of recruitment center

Nuclear Medicine Department of Sayedshohada Hospital in Isfahan

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

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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

Shiraz 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
Esfahan University of Medical Sciences
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Zeinab amirkhani
Position
Nuclear Medicine specialist
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Specialist
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Znbamirkhaninew@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is 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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The results and the data related to the treatment method and how to perform the treatment will be provided to interested people.
When the data will become available and for how long
Access starts 6 months after publication of results
To whom data/document is available
All people interested in the subject of study
Under which criteria data/document could be used
It is accessible by maintaining the confidentiality of the data.
From where data/document is obtainable
Dr. Zainab Amirkhani, email znbamirkhaninew@gmail.Com
What processes are involved for a request to access data/document
The applicants should explain the reason for the request and the method of trust through email, and if the project managers agree, the results will be provided for them.
Comments