

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 evaluated that 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

Country

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 ^{68}Ga -PSMA PET/CT or alternative imaging ($^{99\text{m}}\text{Tc}$ -PSMA)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The multidisciplinary tumor board will decide whether patients were eligible for the treatment with ^{177}Lu -PSMA-617. Patients will be considered eligible if one or more metastases were predominantly PSMA positive on ^{68}Ga -PSMA PET/CT or $^{99\text{m}}\text{Tc}$ -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 the 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 4mg 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 Qaedian

Street address

Nuclear Medicine Department, Namazi Hospital, Namazi Square, Zand Street

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2

Recruitment center

Name of recruitment center

Nuclear Medicine Department of Sayedshohada Hospital in Isfahan

Full name of responsible person

Zeinab Amirkhani

Street address

Seyyed al-Shohada Hospital (AS), Nehar Farshadi Street, Khayam Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Tahere Qaedian

Street address

Nuclear Medicine Department, Namazi Hospital, Namazi Square, Zand Street

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13311 - 71936

Phone

+98 71 3612 5315

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tghaedian@gmail.com

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

Full name of responsible person

Zeinab amirkhani

Position

Nuclear Medicine specialist

Latest degree

Specialist

Other areas of specialty/work

Nuclear Medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Tahere Qaediyan

Position

Master of nuclear medicine

Latest degree

Specialist

Other areas of specialty/work

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City

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Email

tghaedian@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person**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