

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Efficiency of ¹⁷⁷Lu-DOTA-FAPI Therapy in Treatment of Patients With Various Types of Cancer (Primary Locally Advanced or Metastatic Cancers)

Protocol summary

Study aim

To evaluate the efficacy of the ¹⁷⁷Lu-DOTA-FAPI therapy in patients with various types of cancers

Design

This is an interventional, phase 2 clinical trial with 30 patients, enrolled between September 2021 to September 2023, which will be followed between treatment sessions

Settings and conduct

Patients are selected and justified in the nuclear medicine center at the Bushehr Nuclear Medicine department. The consent form is obtained and finally, the treatment will be performed with intravenous injection of 7.4 GBq (200mCi) of ¹⁷⁷Lu-DOTA-FAPI. 24 and 48 hours after injection, patients will be undergone whole-body scan for the assessment of radiotracer distribution. Six to eight weeks after the ¹⁷⁷Lu-DOTA-FAPI therapy, the patients will be visited by oncologists and nuclear medicine physicians and if there was not any toxicity, the next treatment session will be performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with confirmed FAP receptors detected by ⁶⁸Ga-DOTA-FAPI PET/CT or ^{99m}Tc-DOTA-FAPI SPECT, having suitable hematologic parameters and ECOG Status ≤ 2 who are able to provide informed consent. Exclusion criteria: Pregnant or lactating women; significant bleeding within two weeks prior to trial entry; heart disorders; uncontrolled bacterial, viral, or fungal infection; having psychiatric illness/social situations that would interfere with compliance with study requirements.

Intervention groups

We are going to use a single group of patients to evaluate the efficiency of ¹⁷⁷Lu-DOTA-FAPI in treatment of different cancers expressing FAP receptors.

Main outcome variables

Objective Tumour Response Rate - defined as the

proportion of participants with a confirmed complete response (CR) or partial response (PR) divided by the total number of participants.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210612051548N2**

Registration date: **2021-09-28, 1400/07/06**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-28, 1400/07/06**

Update count: **0**

Registration date

2021-09-28, 1400/07/06

Registrant information

Name

Majid Assadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 77 3332 0361

Email address

assadipoya@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2023-09-23, 1402/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficiency of 177Lu-DOTA-FAPI Therapy in Treatment of Patients With Various Types of Cancer (Primary Locally Advanced or Metastatic Cancers)

Public title

177Lu-DOTA-FAPI Therapy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The presence of at least one tumoral lesion detected by 68Ga-DOTA-FAPI PET/CT or 99mTc-DOTA-FAPI SPECT Having hematologic parameters as: (i) Absolute neutrophil count ≥ 1000 cells/mm³; (ii) Platelet count $\geq 100,000$ /mm³; (iii) Hemoglobin ≥ 8 g/dL Participants who sign the informed consent form which was assented according to the guidelines of the Clinical Research Ethics Committee (signed by participant, parent, or legal representative). Eastern Cooperative Oncology Group Performance Status (ECOG) ≤ 2

Exclusion criteria:

Patient had history of class 3 or 4 congestive heart failure (CHF) Patient had clinically significant bleeding within two weeks prior to trial entry (e.g. gastrointestinal bleeding, intracranial bleeding) Pregnant or lactating women Patient have psychiatric illness/social situations that would interfere with compliance with study requirements Patient cannot undergo PET/CT or SPECT scanning because of weight limits Patient had an active, uncontrolled bacterial, viral, or fungal infection(s) requiring systemic therapy.

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

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**

Research Ethics Committees of Bushehr province
university of medical sciences

Street address

Bushehr University of Medical Science, Moallem
Street, Bushehr, Iran

City

Bushehr

Province

Boushehr

Postal code

45654775

Approval date

2021-06-27, 1400/04/06

Ethics committee reference number

IR.BPUMS.REC.1400.045

2**Ethics committee****Name of ethics committee**

Research Ethics Committees of Bushehr province
university of medical sciences

Street address

Bushehr University of Medical Science, Moallem
Street, Bushehr, Iran

City

Bushehr

Province

Boushehr

Postal code

45654775

Approval date

2021-06-27, 1400/04/06

Ethics committee reference number

IR.BPUMS.REC.1400.047

3**Ethics committee****Name of ethics committee**

Research Ethics Committees of Bushehr province
university of medical sciences

Street address

Bushehr University of Medical Science, Moallem
Street, Bushehr, Iran

City

Bushehr

Province

Boushehr

Postal code

45654775

Approval date

2021-06-27, 1400/04/06

Ethics committee reference number

IR.BPUMS.REC.1400.048

4

Ethics committee

Name of ethics committee

Research Ethics Committees of Bushehr province
university of medical sciences

Street address

Bushehr University of Medical Science, Moallem
Street, Bushehr, Iran

City

Bushehr

Province

Boushehr

Postal code

45654775

Approval date

2021-06-27, 1400/04/06

Ethics committee reference number

IR.BPUMS.REC.1400.043

5

Ethics committee

Name of ethics committee

Research Ethics Committees of Bushehr province
university of medical sciences

Street address

Bushehr University of Medical Science, Moallem
Street, Bushehr, Iran

City

Bushehr

Province

Boushehr

Postal code

45654775

Approval date

2021-06-27, 1400/04/06

Ethics committee reference number

IR.BPUMS.REC.1400.046

6

Ethics committee

Name of ethics committee

Research Ethics Committees of Bushehr province
university of medical sciences

Street address

Bushehr University of Medical Science, Moallem
Street, Bushehr, Iran

City

Bushehr

Province

Boushehr

Postal code

45654775

Approval date

2021-06-27, 1400/04/06

Ethics committee reference number

IR.BPUMS.REC.1400.049

7

Ethics committee

Name of ethics committee

Research Ethics Committees of Bushehr province
university of medical sciences

Street address

Bushehr University of Medical Science, Moallem
Street, Bushehr, Iran

City

Bushehr

Province

Boushehr

Postal code

45654775

Approval date

2021-06-27, 1400/04/06

Ethics committee reference number

IR.BPUMS.REC.1400.044

8

Ethics committee

Name of ethics committee

Research Ethics Committees of Bushehr province
university of medical sciences

Street address

Bushehr University of Medical Science, Moallem
Street, Bushehr, Iran

City

Bushehr

Province

Boushehr

Postal code

45654775

Approval date

2021-06-27, 1400/04/06

Ethics committee reference number

IR.BPUMS.REC.1400.042

Health conditions studied

1

Description of health condition studied

Brain tumors

ICD-10 code

C71

ICD-10 code description

Malignant neoplasm of brain

2

Description of health condition studied

Thyroid cancer resistant to radioactive iodine therapy

ICD-10 code

C73

ICD-10 code description

Malignant neoplasm of thyroid gland

3

Description of health condition studied

Gastrointestinal tumor

ICD-10 code

C15-C26

ICD-10 code description

Malignant neoplasms of digestive organs

4**Description of health condition studied**

Lung cancer

ICD-10 code

C34

ICD-10 code description

Malignant neoplasm of bronchus and lung

5**Description of health condition studied**

Prostate cancer

ICD-10 code

C61

ICD-10 code description

Malignant neoplasm of prostate

6**Description of health condition studied**

Malignant female genital organs

ICD-10 code

C57.8

ICD-10 code description

Malignant neoplasm of overlapping sites of female genital organs

7**Description of health condition studied**

Urinary tract cancer

ICD-10 code

C68.9

ICD-10 code description

Malignant neoplasm of urinary organ, unspecified

8**Description of health condition studied**

Breast cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

9**Description of health condition studied**

Malignant neoplasm of head, face and neck

ICD-10 code

C49.0

ICD-10 code description

Malignant neoplasm of connective and soft tissue of head, face and neck

Primary outcomes**1****Description**

Objective Tumour Response Rate - defined as the proportion of participants with a confirmed complete response (CR) or partial response (PR) divided by the total number of participants.

Timepoint

6-8 week after last session of treatment

Method of measurement

Observation and semi-quantification analysis via PET/CT imaging

Secondary outcomes**1****Description**

Progression free survival (PSF)

Timepoint

Average 2 years

Method of measurement

Medical imaging

Intervention groups**1****Description**

Intervention group: In this study, 7.4 GBq (200 mCi) of ¹⁷⁷Lu-DOTA-FAPI is injected intravenously into 30 patients with various types of cancers that demonstrated high FAP expression according to the ⁶⁸Ga-DOTA-FAPI PET/CT or ^{99m}Tc-DOTA-FAPI SPECT. Then whole-body scan is performed at 24 hours, and 48 hours after injection to assess radiotracer distribution. Six to eight weeks after the ¹⁷⁷Lu-DOTA-FAPI therapy, the patients will be visited by oncologists and nuclear medicine physicians and if there was not any toxicity, the next treatment session will be performed.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Persian Gulf Hospital

Full name of responsible person

Majid Assadi

Street address

The nuclear medicine center, Persian Gulf hospital, Taleghani street, Bushehr, Iran

City

Bushehr

Province

Boushehr

Postal code

45654775

Phone

+98 77 3345 5375

Fax

Email

assadipoya@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Gholamreza Khamisipour

Street address

Vice-Chancellor for Research and Technology of
Bushehr University of Medical Sciences, Salman-e-
Farsi Blvd, Bushehr, Iran.

City

Bushehr

Province

Boushehr

Postal code

45654775

Phone

+98 77 3345 0178

Fax

Email

khamisipourgholamreza@gmail.com

Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Boushehr 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

Boushehr University of Medical Sciences

Full name of responsible person

Majid Assadi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Nuclear Medicine

Street address

The Persian Gulf Nuclear Medicine Research Center,
Bushehr University of Medical Sciences, Moallem
Street, Bushehr, Iran

City

Bushehr

Province

Boushehr

Postal code

45654775

Phone

+98 77 3332 0361

Fax

+98 77 3332 0361

Email

assadipoya@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Majid Assadi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Nuclear Medicine

Street address

The Persian Gulf Nuclear Medicine Research Center,
Bushehr University of Medical Sciences, Moallem
Street, Bushehr, Iran

City

Bushehr

Province

Boushehr

Postal code

45654775

Phone

+98 77 3332 0361

Fax

+98 77 3332 0361

Email

assadipoya@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Narges Jokar

Position

Research Instructor

Latest degree

Master

Other areas of specialty/work

Medical Physics

Street address

The Persian Gulf Nuclear Medicine Research Center,
Bushehr University of Medical Sciences, Moallem
Street, Bushehr, Iran

City

Bushehr

Province

Boushehr

Postal code

45654775

Phone

+98 77 3332 0361

Fax

+98 77 3332 0361

Email

narges.jokar69@gmail.com

Web page address

<https://pgnmrc.bpums.ac.ir/fa/index.aspx>

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

Undecided - It is not yet known if there will be 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

When the data will become available and for how long

To whom data/document is available

Under which criteria data/document could be used

From where data/document is obtainable

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

Comments