

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Efficiency of <sup>177</sup>Lu-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 <sup>177</sup>Lu-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 <sup>177</sup>Lu-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 <sup>177</sup>Lu-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 <sup>68</sup>Ga-DOTA-FAPI PET/CT or <sup>99m</sup>Tc-DOTA-FAPI SPECT, having suitable hematologic parameters and ECOG Status  $\leq 2$  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 <sup>177</sup>Lu-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  $\geq 1000$  cells/mm<sup>3</sup>; (ii) Platelet count  $\geq 100,000$ /mm<sup>3</sup>; (iii) Hemoglobin  $\geq 8$  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)  $\leq 2$

**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 <sup>177</sup>Lu-DOTA-FAPI is injected intravenously into 30 patients with various types of cancers that demonstrated high FAP expression according to the <sup>68</sup>Ga-DOTA-FAPI PET/CT or <sup>99m</sup>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 <sup>177</sup>Lu-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**

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**When the data will become available and for how long**

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**To whom data/document is available**

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**Under which criteria data/document could be used**

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**From where data/document is obtainable**

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

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**Comments**