

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Initial evaluation of the therapeutic efficacy of ¹⁷⁷Lu-FAPI in patients with various end-stage metastatic cancers resistant to standard therapies

Protocol summary

Study aim

Initial evaluation of the therapeutic efficacy of ¹⁷⁷Lu-FAPI in patients with various end-stage metastatic cancers resistant to standard therapies

Design

Clinical trial Phase I, One group of patients, with various end-stage metastatic cancers resistant to standard therapies

Settings and conduct

The study is on the palliative treatment of cancer in nuclear medicine using therapeutical radiopharmaceuticals. The study will be performed in Hasheminejad Hospital and Khatam hospital. At first, PET/CT scan using the ⁶⁸Ga-FAPI radiopharmaceutical or SPECT/CT scan using the ^{99m}Tc-FAPI will be performed. The next step is treatment using ¹⁷⁷Lu-FAPI (Beta emitter) intravenously injected. Then the SPECT imaging will show the accumulation sites of radiopharmaceutical. The result of previous steps will determine the continuation of the therapy on individual patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: the patient should be able to understand and sign off the informed consent; the patient should be able to understand and follow the treatment protocol; patients should be older than 18; the patient's life expectancy should be over 6 months; patients should show no response to the standard treatment; the ⁶⁸Ga-FAPI PET scan or ^{99m}Tc-FAPI SPECT scan should show 3 times more uptake of radiopharmaceutical in tumor to the liver of the patients; the patient with the progressive disease.

Intervention groups

Use of radiopharmaceutical ¹⁷⁷Lu-FAPI-46 in the treatment of end-stage patients with metastatic cancer resistant to standard treatments of digestive system or breast

Main outcome variables

Pain feeling scale; patients' ability to perform various ordinary tasks.

General information

Reason for update

"Considering the title change in the registered project in Researcher Page, I deemed it necessary to have the changes made on this website registered as well."

Acronym

IRCT registration information

IRCT registration number: **IRCT20211206053304N1**

Registration date: **2022-08-22, 1401/05/31**

Registration timing: **prospective**

Last update: **2023-07-26, 1402/05/04**

Update count: **1**

Registration date

2022-08-22, 1401/05/31

Registrant information

Name

Leila Hassanzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 5503

Email address

hassanzadeh.l@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2023-03-19, 1401/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Initial evaluation of the therapeutic efficacy of ¹⁷⁷Lu-FAPI in patients with various end-stage metastatic cancers resistant to standard therapies

Public title

¹⁷⁷Lu-FAPI in cancer therapy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

the patient should be able to understand and sign off the informed consent. The patient should be able to understand and follow the treatment protocol. Patients should be older than 18. The patients life expectancy should be over 6 months. patients should show no response to the standard treatment. The ⁶⁸Ga-FAPI PET scan or ^{99m}Tc-FAPI SPECT scan should show 3 times more uptake of radiopharmaceutical in tumor to liver of the patients. the patient with progressive disease should be included.

Exclusion criteria:

The patients who have received therapeutic radiopharmaceuticals like, ²²³Ra, ¹⁸⁸Re, ¹⁸⁶Re, ¹⁵³Sm during last 6 months. The patients are under systemic therapies like chemotherapy, immunotherapy, or biological treatment for cancer. The patients who have been under any research treatment during 28 days before entrance in this study. The patients who have shown any known allergy to the therapeutic radiopharmaceuticals. The patients who have congestive heart failure.

Age

From **18 years** old

Gender

Both

Phase

1

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**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

Street address

No. 3, Homa Alley, Hafezi Ave., Farahzadi Blvd., Qods Town.

City

Tehran

Province

Tehran

Postal code

1468793336

Approval date

2022-08-02, 1401/05/11

Ethics committee reference number

IR.IUMS.FMD.REC.1401.248

Health conditions studied**1****Description of health condition studied**

end-stage metastatic gastrointestinal or breast cancer

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Amount of pain feeling on the bone

Timepoint

Just before treatment and every 4 weeks after treatment.

Method of measurement

Using Visual Analogue Scale questionnaire

2**Description**

Performance Status (quality of life)

Timepoint

Before treatment and every 4 weeks after treatment.

Method of measurement

Eastern Cooperative Oncology Group (ECOG)
Performance Status

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: the selected patients go through PET/CT (68Ga-FAPI radiopharmaceutical about 6 mCi dose) or SPECT/CT (99mTc-FAPI radiopharmaceutical about 20 mCi dose) scan at first. The therapeutic 177Lu-FAPI radiopharmaceutical (about 86 mCi) will be injected. the manufacture of the radiopharmaceuticals is Pars Isotope company. Then the scintigraphy will be done to show the radiopharmaceutical accumulation sites. based on the results of the study additional treatment will be evaluated and determined.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram Hospital

Full name of responsible person

Dr. Nastaran Khodakarim

Street address

Sattarkhan Ave., Niyayesh Ave., Mansoori Ave.

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Rasoolhospital@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Hosain Keyvani

Street address

Next to Milad Tower, Hemmat freeway

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info@iums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Leila Hassanzadeh

Position

Assisstan Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nuclear Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Leila Hassanzadeh

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nuclear Medicine

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Person responsible for updating data

Contact

Name of organization / entity
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Other areas of specialty/work
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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not 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

Undecided - It is not yet known if there will be 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

Not applicable