

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

Evaluation the efficiency of 99mTc-FAPI radiotracer in diagnosis of patients suffering from cancer

Protocol summary

Study aim

The diagnostic efficacy of 99mTc-FAPI SPECT/CT in the diagnosis of malignant tumors

Design

This is an interventional clinical trial with a single group design of 15 patients, performing between February 2022 and March 2023.

Settings and conduct

Patients with inclusion criteria are selected and justified in the nuclear medicine center of the Khalij-e-Fars Hospital at Bushehr. The consent form is obtained. The diagnosis will be performed with intravenous injection of 99mTc-FAPI and imaging was performed at different 1 and 4 hours post-injection.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Volunteering to participate in clinical trials and signing an informed consent form, Patients with suspected or newly diagnosed or previously treated malignant tumors, Inconclusive findings on imaging modalities. Exclusion criteria: Pregnant and lactating women, the inability or unwillingness of the participant, parent, or legal representative to provide written informed consent.

Intervention groups

In this trial, 740 MBq of the 99mTc-FAPI will be injected intravenously. Then, SPECT/CT imaging will be performed at 1 and 4 h after tracer administration of radiotracer.

Main outcome variables

Target/Background ratio of 99mTc-FAPI in the diagnosis of malignancies.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210612051548N5**

Registration date: **2022-01-29, 1400/11/09**

Registration timing: **prospective**

Last update: **2022-01-29, 1400/11/09**

Update count: **0**

Registration date

2022-01-29, 1400/11/09

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

2022-03-06, 1400/12/15

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the efficiency of 99mTc-FAPI radiotracer in diagnosis of patients suffering from cancer

Public title

Diagnostic efficacy of 99mTc-FAPI SPECT/CT

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

Volunteering to participate in clinical trials and signing

an informed consent form (signed by participant, parent, or legal representative) Patients with suspected or new diagnosed or previously treated malignant tumors Inconclusive findings on imaging modalities.

Exclusion criteria:

Pregnant and lactating women The inability or unwillingness of the research participant, parent, or legal representative to provide written informed consent

Age

From **18 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **15**

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 University of Medical Sciences

Street address

Bushehr University of Medical Science, Moallem Street

City

Bushehr

Province

Boushehr

Postal code

45654775

Approval date

2021-06-27, 1400/04/06

Ethics committee reference number

IR.BPUMS.REC.1400.056

Health conditions studied

1

Description of health condition studied

Malignant neoplasm

ICD-10 code

C00-C96

ICD-10 code description

Malignant neoplasm

Primary outcomes

1

Description

Target/Background ratio of 99mTc-FAPI SPECT/CT in Diagnosis of malignancies.

Timepoint

99mTc-FAPI Imaging at 1and 4 hours after the administration of the Radiotracer.

Method of measurement

SPECT/CT scanner

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The majority of epithelial tumors recruit fibroblasts and other non-malignant cells and activate them into cancer-associated fibroblasts. This often leads to overexpression of the membrane serine protease fibroblast-activating protein (FAP). It has already been shown that DOTA-bearing FAP inhibitors (FAPis) generate high contrast images with PET/CT scans. Since SPECT is a lower cost and more widely available alternative to PET, 99mTc-labeled FAPis represent attractive tracers for imaging applications in a larger number of patients. In this clinical trial, 740 MBq of the 99mTc-FAPI will be injected intravenously. Then, SPECT/CT will be performed at 1 and 4 h after tracer administration of radiotracer.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Nuclear Medicine Center, Khalig-e-Fars Hospital

Full name of responsible person

Majid Assadi

Street address

Khalig-e-Fars Hospital, Taleghani Street

City

Bushehr

Province

Boushehr

Postal code

45654775

Phone

+98 77 3332 0361

Email

assadipoya@yahoo.com

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 Khalij-e-Fars 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 Khalij-e-Fars 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 Khalij-e-Fars 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

Undecided - It is not yet known if there will be 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

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

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