Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Evaluation of the diagnostic value of 68Ga-FAPI radiotracer compared with 18F-FDG in PET/CT scans of patients with non-small cell lung cancer- a pilot study

Protocol summary

Study aim
Determining the efficiency of 68Ga-FAPI PET-CT scanning in the diagnosis of active tumoral lesions of lung cancer

Design
Self-controlled clinical study , non-randomized, phase 2 on 20 patients.

Settings and conduct
18F-FDG imaging will be done based on the standard protocol in the nuclear medicine department of Masih Daneshvari Hospital. 68Ga-FAPI PET-CT scan will be performed with a maximum interval of one month from 18F-FDG PET-CT. 68Ga-FAPI will be injected IV with a dose of 3.3-4.8 millicuries. 60 minutes later, a vertex to mid-thigh image will be taken. The lesions are compared one by one in terms of their characteristics between 18F-FDG PET-CT and 68Ga-FAPI PET-CT scans and the detection rate is calculated.

Participants/Inclusion and exclusion criteria
Patients with lung cancer in staging phase proven by pathology Patients do not accept the offer of PET-CT with 68Ga-FAPI radiopharmaceutical, give up, or receive medical intervention in the interval between two scans, are excluded from the study.

Intervention groups
In order to determine the effectiveness of 68Ga-FAPI PET-CT scan in the detection of malignant lesions of lung cancer, the patients will be undergone with 68Ga-FAPI radiopharmaceutical after 18FDG scan and their results will be analyzed.

Main outcome variables
Number of malignant lesions; Localization of malignant lesions; Size of malignant lesions; Shape of malignant lesions and Tumor to background ratio

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220817055732N1**
Registration date: **2022-09-26, 1401/07/04**
Registration timing: **prospective**

Last update: **2022-09-26, 1401/07/04**
Update count: **0**

Registration date
2022-09-26, 1401/07/04

Registrant information

Name
Hossein Behnammanesh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 2712 2701

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-10-23, 1401/08/01

Expected recruitment end date
2023-10-23, 1402/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the diagnostic value of 68Ga-FAPI

radiotracer compared with 18F-FDG in PET/CT scans of patients with non-small cell lung cancer- a pilot study

Public title
Evaluation of 68Ga-FAPI radiotracer in lung cancer
Purpose
Diagnostic
Inclusion/Exclusion criteria
Inclusion criteria:
A patient with lung cancer proven in pathology A patient with lung cancer in the staging phase
Exclusion criteria:
Patients do not accept the offer of PET-CT with 68Ga-FAPI radiopharmaceutical after providing the necessary explanations and answering their questions. Patients withdraw from the study before the scan. Uncontrolled diseases (such as fatal arrhythmias) that require hospitalization. Suffering from mental illnesses that take away the ability to make decisions and cooperate. Pregnant or lactating women. Suffering from physical diseases that disrupt the imaging process. The death of the patient in the interval between the two studied scans. History of cancer other than lung cancer History of active inflammatory/infectious disease
Age
No age limit
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **20**
More than 1 sample in each individual
Number of samples in each individual: **2**
PET-CT scan with 18F-FDG and 68Ga-FAPI radiopharmaceuticals separately for each participant
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 Shahid Beheshti University of Medical Sciences
Street address
7th Floor, Bldg No.2, SBMU, Velenjak
City
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Province
Tehran
Postal code
1985717443
Approval date
2022-08-17, 1401/05/26
Ethics committee reference number
IR.SBMU.NRITLD.REC.1401.073

Health conditions studied

1

Description of health condition studied
Lung cancer
ICD-10 code
C34
ICD-10 code description
Malignant neoplasm of bronchus and lung

Primary outcomes

1

Description
The number of malignant lesions in selected patients
Timepoint
After PET-CT imaging of the patients with 18FDG and 68Ga-FAPI radiotracers
Method of measurement
Investigation of PET-CT scans

2

Description
Localization of malignant lesions in selected patients
Timepoint
After PET-CT imaging of the patients with 18FDG and 68Ga-FAPI radiotracers
Method of measurement
Investigation of PET-CT scans

3

Description
Size of malignant lesions in selected patients
Timepoint
After PET-CT imaging of the patients with 18FDG and 68Ga-FAPI radiotracers
Method of measurement
Investigation of PET-CT scans

4

Description
Shape of malignant lesions in selected patients
Timepoint
After PET-CT imaging of the patients with 18FDG and

68Ga-FAPI radiotracers

Method of measurement

Investigation of PET-CT scans

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patients with lung cancer referred to this center after 18F-FDG are selected non-randomly after receiving full explanations and personal consent to perform a second diagnostic scan with 68Ga-FAPI radiotracer produced by Pars Isotope Company. 68Ga-FAPI scan with a dose of about 2 MB/kg of the patient's weight is performed at a maximum interval of one month after the 18FDG scan. After the injection of the radiopharmaceutical, the patient waits for one hour until the radiopharmaceutical be absorbed in the target tissues. After that, the scan of the mid-thigh is performed with a PET-CT Discovery 690 VCT device from GE Healthcare equipped with CT 64 slice for 30 minutes. Data obtained from PET-CT imaging are reconstructed using a standard algorithm with attenuation correction based on CT scan data. During this interval between two scans, the patient will not receive any medical intervention.

Category

Diagnosis

2

Description

Control group: I patients with lung cancer refered to the Nuclear Medicine Center of Masih Daneshvari Hospital for a diagnostic PET-CT scan. 18FDG scan with 18FDG radiopharmaceutical produced in the cyclotron department of this hospital is performed according to the international standard protocol. 68Ga-FAPI scan with a dose of about 2 MB/kg of the patient's weight is performed at a maximum interval of one month after the 18FDG scan. After the injection of the radiopharmaceutical with a dose 4.6 Megabecquerel (MBq) per kilogram , the patient waits for one hour until the radiopharmaceutical be absorbed in the target tissues. After that, the scan of the mid-thigh is performed with a PET-CT Discovery 690 VCT device from GE Healthcare equipped with CT 64 slice for 30 minutes. Data obtained from PET-CT imaging are reconstructed using a standard algorithm with attenuation correction based on CT scan data.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Masih-daneshvari hospital

Full name of responsible person

Abtin Doroudinia

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Deputy of research and technology

Street address

5th floor, building No-2, SBUMS, velenjak

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

45

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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
hossein behnam-manesh

Position
assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
nuclear pharmacy

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Person responsible for scientific inquiries

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Position
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Specialist

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Nuclear Medicine

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Person responsible for updating data

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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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
1. The statistical data obtained from the comparison of 18FDG and 68Ga-FAPI scans, which show their diagnostic value in finding primary active lesions of lung cancer. 2. Comparative PET-CT scan images with 18FDG and 68Ga-FAPI radiotracers obtained from patients 3. Study protocol 4. Basic characteristics of patients

When the data will become available and for how long
The end of study

To whom data/document is available
Nuclear Medicine - Nuclear Pharmacy - Oncologist - Companies producing radiopharmaceuticals

Under which criteria data/document could be used
1. The obtained data may be used for further evaluation of 18Ga-FAPI radiopharmaceutical in other tumor lesions or other diseases. 2. The obtained clinical data may be used to register 18Ga-FAPI radiotracer as a new diagnostic radiopharmaceutical in lung cancer.

From where data/document is obtainable
1. Dr Abtin Drudinia- Nuclear Medicine center of Masih Danehvari hospital- abtin1354@gmail.com 2. Dr Hossein Behnammanesh- Nuclear Medicine center of Masih Danehvari hospital- h_behnam@sbmu.ac.ir

What processes are involved for a request to access data/document
After the end of the project, the obtained data will be published in related scientific journals and will be available in this way.

Comments