Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Oct 2026

Evaluating diagnostic value of 99mTc-CXCR4 scan in differentiation of high-grade and low-grade glioma

Protocol summary

Study aim
Clinical use of 99mTc-CXCR4 radiopharmaceutical in glioblastoma patients

Design
In this study, 15 patients with primary diagnosis of glioma based on clinical criteria and radiological imaging, who referred to Namazi or Chamran hospital for surgery and have the conditions to enter the study, were selected and before surgery, they were referred to the nuclear medicine department of Namazi hospital.

Settings and conduct
Patients who meet the conditions for entering the study are sent to the nuclear medicine department of Shiraz Namazi Hospital. Intravenous injection of radiopharmaceutical is done for each patient and after 3 hours of injection, imaging is done. The pathology results of the patients after surgery are compared with the scan results.

Participants/Inclusion and exclusion criteria
Patients with primary diagnosis of glioma based on clinical criteria and radiological imaging. The criteria for entering the study include the following patients: glioma has been diagnosed based on MRI within the last month; the patient is a candidate for surgical resection and has not undergone any type of anti-cancer treatment; the patient's condition is stable to perform the scan, the patient is ready to perform the scan have consent and are not pregnant or breastfeeding at the time of the scan. Exclusion criteria include patients with multiple masses; patients who need emergency interventions after initial diagnosis; patients whose tumor cannot be operated and patients who do not consent to scan or surgery.

Intervention groups
In this study, a group of patients was used to evaluate the applicability of 99mTc-CXCR4 radiopharmaceutical in the diagnosis of glioblastoma.

Main outcome variables
The average absorption of radiopharmaceuticals in glioblastoma; the sensitivity of 99mTc-CXCR4 scanning; the specificity of 99mTc-CXCR4 scanning

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230703058654N1**
Registration date: **2023-10-22, 1402/07/30**
Registration timing: **prospective**

Last update: **2023-10-22, 1402/07/30**
Update count: **0**

Registration date
2023-10-22, 1402/07/30

Registrant information

Name
tahereh firuzyar

Name of organization / entity

Country
Iran (Islamic Republic of)

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firuzyar@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-04-20, 1403/02/01

Expected recruitment end date
2024-09-22, 1403/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating diagnostic value of 99mTc-CXCR4 scan in differentiation of high-grade and low-grade glioma

Public title
Evaluating diagnostic value of 99mTc-CXCR4 scan in glioblastoma

Purpose
Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:
The patient has been diagnosed with glioma based on MRI within the last month The patient is a candidate for surgical resection and has not undergone any type of anti-cancer treatment The patient's condition is stable for the scan The patient consents to the scan, and at the time of the scan Do not be pregnant or breastfeeding

Exclusion criteria:
Patients with multiple masses Patients who need emergency interventions after initial diagnosis Patients whose tumor cannot be operated Patients who do not consent to scan or surgery

Age
From **18 years** old

Gender
Both

Phase
1-2

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
Expert Committee on Ethics in Biomedical Research, Faculty of Medicine, Shiraz University of Medical

Street address
Vice-Chancellor of the Medical School, 3rd Floor, Building No. 3, School of Medicine, Imam Hossein square, Zand St.

City
Shiraz

Province
Fars

Postal code
7134845794

Approval date
2023-09-03, 1402/06/12

Ethics committee reference number
IR.SUMS.MED.REC.1402.238

Health conditions studied

1

Description of health condition studied
Glioblastoma

ICD-10 code
C71.9

ICD-10 code description
Malignant neoplasm of brain, unspecified

Primary outcomes

1

Description
The mean amount of radioactivity uptake in low-grade glioma patients

Timepoint
3 hours after radiopharmaceutical administration

Method of measurement
SPECT/CT imaging

2

Description
The mean amount of radioactivity uptake in high-grade glioma patients

Timepoint
3 hours after radiopharmaceutical administration

Method of measurement
SPECT/CT imaging

3

Description
Sensitivity of imaging to detect high-grade glioma

Timepoint
3 hours after radiopharmaceutical administration

Method of measurement
SPECT/CT imaging and comparison with pathology results

4

Description
Sensitivity of imaging to detect low-grade glioma

Timepoint
3 hours after radiopharmaceutical administration

Method of measurement

SPECT/CT imaging and comparison with pathology results

Secondary outcomes

empty

Intervention groups

1

Description
The intervention groups include glioblastoma patients whose mass has been proven by imaging methods such as MRI. This evaluation is a diagnostic method using the single photon emission computed tomography (SPECT) modality, in which the radiopharmaceutical 99mTCc-CXCR4 is injected into patients at a dose of 20 millicuries. The CXCR4 peptide is produced as a kit by the Atomic Energy Organization and all chemical and bacterial purity tests are checked on it. The desired radiopharmaceutical is labeled in Namazi Hospital, Shiraz, and its radiochemical purity is checked and confirmed before injection to the patient. This radiopharmaceutical is injected intravenously to patients once. The place of injection is the nuclear medicine department of Shiraz Namazi Hospital, where there are necessary medical equipment and also a doctor for prevention and treatment in case the patient has complications caused by the injection. The results of the imaging are finally compared with the pathology results after surgery.

Category
Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center
Namazi hospital

Full name of responsible person
Dr. Tahereh Firuzyar

Street address
Namazi hospital, Namazi Square, Zand St.

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Shiraz

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7193613311

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Dr. Mohammad hashem Hashempour

Street address
7th floor, central building of Shiraz University of Medical Sciences, Zand St

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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
Shiraz University of Medical Sciences

Proportion provided by this source
50

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

2

Sponsor

Name of organization / entity
Nuclear Science and Technology Research Institute

Full name of responsible person
Dr. Mostafa Erfani

Street address
Nuclear Science and Technology Research Institute, North Kargar Ave

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Tehran

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1439955933

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mgandomkar@aeoi.org.ir

Grant name

Grant code / Reference number

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

Title of funding source
Nuclear Science and Technology Research Institute

Proportion provided by this source
50
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
Shiraz University of Medical Sciences
Full name of responsible person
Dr. tahereh firuzyar
Position
Assistant Professor
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radiopharmacy
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Person responsible for updating data

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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
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