

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Sep 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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+98 71 3612 5387

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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.

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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 ^{99m}Tc-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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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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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

Latest degree

Ph.D.

Other areas of specialty/work

radiopharmacy

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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

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