

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Sep 2026

Quantitative Investigation of Brain Glioma Tumor Changes After Radiation Therapy by 3D Comparative Method Using MRI Diffusion Images about predicting response to treatment

Protocol summary

Study aim

Evaluation of the methods of MRI (DWI-MRS) to detect the Response to treatment and Pseudo-Progression

Design

A clinical trial with a control group, randomized on 75 patients with various types of glioma using statistical random numbers, blinded.

Settings and conduct

The study will be conducted on glioma cancer patients referred to the radiotherapy department of Milad Hospital in Isfahan. In this way, the patients are not aware of the difference in the diagnostic protocol used to evaluate the response to the treatment (blinded).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with types of glioma
Exclusion criteria: With central nervous system disease, inability to continue the treatment process

Intervention groups

Intervention group: using the newly designed multi-stage diagnostic process and examining the changes in its quantitative factors to correctly predict the treatment outcome of different types of Glioma cells
Control group: not using treatment method to predict treatment outcome using the experimental method

Main outcome variables

Estimation of all quantitative indices of interventional diagnosis: Diffusion-weighted (DWI) included ADC
Metabolic imaging (MRS) included (Cho/Cr-NAA/Cr-Cho/NAA) Ratios And their relationship with the changes in tumor therapeutic volumes based on the RANO criterion and characteristics to evaluate the results

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230904059352N1**

Registration date: **2023-09-26, 1402/07/04**

Registration timing: **registered_while_recruiting**

Last update: **2023-09-26, 1402/07/04**

Update count: **0**

Registration date

2023-09-26, 1402/07/04

Registrant information

Name

Maryam Zamanian

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Quantitative Investigation of Brain Glioma Tumor Changes After Radiation Therapy by 3D Comparative Method Using MRI Diffusion Images about predicting

response to treatment	IR.ARI.MUI.REC.1400.099
Public title Examining the response to chemo-radiotherapy treatment of Glioma tumor using MRI method versus Experimental method	Health conditions studied
Purpose Diagnostic	<u>1</u>
Inclusion/Exclusion criteria Inclusion criteria: Patients suffering from types of glioma Exclusion criteria: Tumor recurrence and history of RT-CRT treatment Central Nervous System (CNS) disorders such as epilepsy and stroke Patients with missing data Patients whose total resection of the Tumor was not possible and left the follow-up study due to Disease recurrence and the need for special treatment.	Description of health condition studied Glioma cancer ICD-10 code G96.9 ICD-10 code description Disorder of central nervous system, unspecified
Age No age limit	Primary outcomes
Gender Both	<u>1</u>
Phase N/A	Description Accuracy of predicting response to chemo-radiotherapy (to detect improvement, progression, pseudo-progression)
Groups that have been masked <i>No information</i>	Timepoint One-six month after treatment
Sample size Target sample size: 75	Method of measurement Magnetic Response imaging - Response Assessment in Neuro-Oncology (RANO) Criteria
Randomization (investigator's opinion) N/A	Secondary outcomes
Randomization description	<u>1</u>
Blinding (investigator's opinion) Not blinded	Description Therapeutic volumes based on RANO criteria
Blinding description	Timepoint One and six months after chemo-radiotherapy
Placebo Not used	Method of measurement The values of quantitative MRI indicators and treatment volumes can be calculated automatically by the software. The RANO Criteria is a decision-making rule in relation to the volumes and response to treatment
Assignment Single	
Other design features	
Secondary Ids empty	Intervention groups
Ethics committees	<u>1</u>
<u>1</u>	Description Intervention group: use of multiple MRI diagnostic methods (differentiating glioma cell types) to predict response to treatment based on changes in treatment volumes - control group: No use of multiple diagnostic methods and protocols to predict response to treatment and use of experimental method
Ethics committee Name of ethics committee Isfahan university of medical sciences Street address Hezar jarib City Isfahan Province Isfahan Postal code 8174673461	Category Diagnosis
Approval date 2022-02-23, 1400/12/04	Recruitment centers
Ethics committee reference number	<u>1</u>
	Recruitment center Name of recruitment center

Milad Hospital Radiotherapy Center
Full name of responsible person
Iraj Abedi
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Sponsors / Funding sources

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Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
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81746-73441
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askari@mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person

Iraj Abedi
Position
Faculty of department medical physic
Latest degree
Ph.D.
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Person responsible for scientific inquiries

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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

Undecided - It is not yet known if there will be 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

The data includes the Excel file for collecting quantitative values of MRI methods.

When the data will become available and for how long

After the publication of the article related to the study

To whom data/document is available

Request from the person in charge of the study and article and provide logical reasons.

Under which criteria data/document could be used

Other similar studies

From where data/document is obtainable

Researchers can contact the person in charge of the study (Dr. Iraj Abedi) via email at i.abedi@med.mui.ac.ir to receive documents or study data.

What processes are involved for a request to access data/document

Researchers can easily get the study data in the shortest time by sending an email to the person in charge of the study.

Comments