

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 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)

Phone

+98 66 3352 0176

Email address

m.zamanian@resident.mui.ac.ir

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

Purpose

Diagnostic

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.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 75

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

Isfahan university of medical sciences

Street address

Hezar jarib

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2022-02-23, 1400/12/04

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Glioma cancer

ICD-10 code

G96.9

ICD-10 code description

Disorder of central nervous system, unspecified

Primary outcomes

1

Description

Accuracy of predicting response to chemo-radiotherapy (to detect improvement, progression, pseudo-progression)

Timepoint

One-six month after treatment

Method of measurement

Magnetic Response imaging - Response Assessment in Neuro-Oncology (RANO) Criteria

Secondary outcomes

1

Description

Therapeutic volumes based on RANO criteria

Timepoint

One and six months after chemo-radiotherapy

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

Intervention groups

1

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

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Milad Hospital Radiotherapy Center
Full name of responsible person
Iraj Abedi
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Phone
+98 31 3778 3000
Email
info@miladhospital.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Gholamreza Asgari
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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
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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