

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 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  
**Street address**  
Janbazan  
**City**  
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**Province**  
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info@miladhospital.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Gholamreza Asgari  
**Street address**  
Hezar jarib  
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**Province**  
Isfahan  
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81746-73441  
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**Email**  
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.  
**Other areas of specialty/work**  
Medical Physics  
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i.abedi@med.mui.ac.ir

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
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## Person responsible for updating data

#### Contact

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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**