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) Rations 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

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
Isfehan
Postal code
8174673461
Approval date
2022-02-23, 1400/12/04
Ethics committee reference number
IR.ARI.MUI.REC.1400.099

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
Isfahan
Province
Isfehan
Postal code
۸۱۷۹۶۶۳۴۶۷
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
Street address
Hezar jarib
City
Isfahan
Province
Isfehan
Postal code
81746-73441
Phone
+98 31 3792 3060
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
Street address
Hezar jarib
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 9011
Email
i.abedi@med.mui.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Maryam Zamanian
Position
Student
Latest degree
Master
Other areas of specialty/work
Medical Physics
Street address
Hezar jarib
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
0632520176
Email
zamanianmary88@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Maryam Zamanian
Position
Student
Latest degree
Master
Other areas of specialty/work
Medical Physics
Street address
Hezar jarib

City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 66 3252 0176
Email
zamanianmary88@yahoo.com

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