Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of treatment outcomes and failure pattern in high grade glioma treated with adjuvant radiotherapy based on standard protocol of RTOG versus smaller margin

Protocol summary

Study aim
Comparison of recurrence pattern and treatment outcomes in patients with high-grade glioma managed by adjuvant radiotherapy based on standard protocol of RTOG with treatment by smaller margin.

Design
A randomized phase 3 clinical trial ,with single-blinded outcome assessment, with a parallel group design of 192 patients . randomization will carry out with block randomization.

Settings and conduct
This study will be done as a multicenter trial in Mashhad ,Tehran, Babol and Sabzevar cities. Patients participating in this trial will be blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Newly diagnosed patients with glioblastoma and anaplastic astrocytoma and oligodendroglioma who have pathology evidence Age 18-75 years KPS≥70% Exclusion criteria: Uncontrolled comorbidities such as diabetes or hypertension that make radiotherapy and chemotherapy infeasible Impossibility of surgery and sampling

Intervention groups
Patients in the intervention group will undergo radiotherapy to the lesion (46 gray dose in 23 fractions to a margin of 1 cm to the high signal region in the , T2/ FLAIR sequences in MRI (residual tumor plus tumor bed removed plus surrounding edema) and boost dose to total of 60 gray to a 1cm margin to the enhancive lesion in the T1 weighted MRI (residual tumor) and tumor bed. Patients in the control group (Based on the RTOG protocol)will undergo radiotherapy to the lesion (46 gray dose in 23 fractions to a margin of 2 cm to the high signal region in the T2/ FLAIR sequences in MRI (residual tumor plus tumor bed removed plus surrounding edema) and boost dose to total of 60 gray to a 2cm margin to the enhancive lesion in the T1 weighted MRI (residual tumor) and tumor bed.

Main outcome variables
Overall survival Progression free survival Pattern of failure

General information

Reason for update

Acronym
MRRG

IRCT registration information
IRCT registration number: **IRCT20210215050367N1**
Registration date: **2021-03-19, 1399/12/29**
Registration timing: **prospective**

Last update: **2021-03-19, 1399/12/29**
Update count: **0**

Registration date
2021-03-19, 1399/12/29

Registrant information

Name
parisa rabiei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3842 6082

Email address
rabieep971@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-04, 1400/01/15

Expected recruitment end date
2024-02-19, 1402/11/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of treatment outcomes and failure pattern in high grade glioma treated with adjuvant radiotherapy based on standard protocol of RTOG versus smaller margin

Public title
Margin reduction in radiotherapy of high grade glioma
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Newly diagnosed glioblastoma multiform patients Newly diagnosed anaplastic astrocytoma patients Newly diagnosed oligodendroglioma patients Confirmed diagnosis based on pathologic evaluation Karnofsky performance index more than 70%
Exclusion criteria:
Uncontrolled diabetes Uncontrolled high blood pressure Impossibility of surgery and tissue sampling
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **192**
Randomization (investigator's opinion)
Randomized
Randomization description
Using the www.sealedenvelope.com website, a block randomization list with block size of 4 (2:2), including group A (intervention) and group B (control) will be created. In this context, numbers will be arranged into AABB, BBAA, ABAB, BABA blocks based on the sequence generated by the site and participants will be enrolled into each group randomly.
Blinding (investigator's opinion)
Single blinded
Blinding description
At time of entry to trial and obtaining informed consent, patients will be informed that they may be either in control or intervention group and they will be blind about their treatment group. In this context, the patient will not aware the amount margins on the treatment planning, however, since the corresponding physician is responsible for treatment planning, his/her blandness will bee impossible. Therefore, this study will be conducted in a single blinded fashion.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Omid hospital, Alandasht crossroad ,Koohsangi avenue
City
Mashhad
Province
Razavi Khorasan
Postal code
۹۱۷۶۶۱۳۷۷۵
Approval date
2020-11-30, 1399/09/10
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1399.711

Health conditions studied

1

Description of health condition studied
High grade glioma
ICD-10 code
C71
ICD-10 code description
Malignant neoplasm of brain

Primary outcomes

1

Description
Progression free survival
Timepoint
At the beginning of the study and then every 3 months in the first year and every 6 months in the following years.
Method of measurement
Physical exam and MRI

Secondary outcomes

1

Description
overall survival
Timepoint
Every 3 month in the first year and every 6 month in

subsequent years

Method of measurement

Physical exam and MRI

2

Description

Pattern of failure

Timepoint

Every 3 month in the first year and every 6 month in subsequent years.

Method of measurement

Physical exam and MRI

Intervention groups

1

Description

Intervention group: intervention group will undergo radiotherapy to the lesion (46 gray dose in 23 fractions to a margin of 1 cm to the high signal region in the , T2/ FLAIR sequences in MRI (residual tumor plus tumor bed removed plus surrounding edema) and boost dose to total of 60 gray to a 1cm margin to the enhancive lesion in the T1 weighted MRI (residual tumor) and tumor bed.

Category

Treatment - Other

2

Description

Control group: Patients in the control group (Based on the RTOG protocol)will undergo radiotherapy to the lesion (46 gray dose in 23 fractions to a margin of 2 cm to the high signal region in the T2/ FLAIR sequences in MRI (residual tumor plus tumor bed removed plus surrounding edema) and boost dose to total of 60 gray to a 2cm margin to the enhancive lesion in the T1 weighted MRI (residual tumor) and tumor bed.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Parisa Rabiei

Street address

Emamreza Sq., Ebn-e-sina Ave.

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3854 3031

Email

emamreza@mums.ac.ir

2

Recruitment center

Name of recruitment center

Omid Hospital

Full name of responsible person

Parisa Rabiei

Street address

Alandasht crossroad, Koohsangi Ave.

City

Mashhad

Province

Razavi Khorasan

Postal code

9176613775

Phone

+98 51 3842 6082

Email

omidhos@mums.ac.ir

3

Recruitment center

Name of recruitment center

Vasei Hospital

Full name of responsible person

Seyed Alireza Javadinia

Street address

Tohid Shahr Blvd.

City

Sabzevar

Province

South Khorasan

Postal code

9617747431

Phone

+98 51 4465 1300

Fax

Email

vasei.h@medsab.ac.ir

4

Recruitment center

Name of recruitment center

Emam Khomeini Hospital

Full name of responsible person

Mostafa Farzin

Street address

Dr Gharib Ave., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6119 0000

Email

imamhospital@tums.ac.ir

5

Recruitment center
Name of recruitment center
Shahid Rajaei Hospital
Full name of responsible person
Danial Fazilatpanah
Street address
Shariati Ave.
City
Babol
Province
Mazandaran
Postal code
4717647745
Phone
+98 11 3528 9259
Fax
+98 11 3528 9262
Email
rajaee@mubabol.ac.ir

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Recruitment center
Name of recruitment center
Reza Radiotherapy & Oncology Center
Full name of responsible person
Kazem Anvari
Street address
Rafsanjani 19 ,17th Azar square , Shahrak Gharb
City
Mashhad
Province
Razavi Khorasan
Postal code
9184166759
Phone
+98 51 3500 8715
Email
Info@rroc.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
University Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 1538
Email
vcresraech@mums.ac.ir

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Parisa Rabiei
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
oncology
Street address
Omid hospital, Alanandasht Crossroad,Kuhsangi Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9176613775
Phone
+98 51 3842 6082
Email
rabieep971@mums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Kazem Anvari
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
oncology
Street address
Omid hospital, Aalndasht Crossroad, Kuhsangi Street

City
Madshhad
Province
Razavi Khorasan
Postal code
9176613775
Phone
+98 51 3842 6082
Email
anvarik@mums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Parisa Rabiei
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
oncology
Street address
Omid hospital , Alandasht Crossroad,Kuhsangi Street,
City
Mashhad
Province
Razavi Khorasan
Postal code
9176613775
Phone
0095 51 38426082
Email
rabieep971@mums.ac.ir

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
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
Title and more details about the data/document
Study protocol, patients data (without identity information) and analysis data will be shared.
When the data will become available and for how long
After the publication of article
To whom data/document is available
Researchers and physicians
Under which criteria data/document could be used
After sending an official request to the corresponding person (Dr Anvari)
From where data/document is obtainable
Through email communication
What processes are involved for a request to access data/document
After receiving the request through email, Dr Anavri will send the requested data.
Comments