

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 \geq 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 enhance 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 enhance 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 blindness will be 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

9176613770

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 enhance 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 enhance 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

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

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Recruitment center

Name of recruitment center

Vasei Hospital

Full name of responsible person

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Recruitment center

Name of recruitment center

Emam Khomeini Hospital

Full name of responsible person

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5

Recruitment center

Name of recruitment center

Shahid Rajaei Hospital

Full name of responsible person

Danial Fazilatpanah

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Recruitment center

Name of recruitment center

Reza Radiotherapy & Oncology Center

Full name of responsible person

Kazem Anvari

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Rafsanjani 19 ,17th Azar square , Shahrak Gharb

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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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

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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

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Person responsible for updating data**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

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Latest degree

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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

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