Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Oct 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

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Iran (Islamic Republic of)

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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
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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

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2

Recruitment center

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3

Recruitment center

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Vasei Hospital

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Recruitment center

Name of recruitment center

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5

Recruitment center
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Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
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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
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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
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