

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

A single-blind, randomized, clinical trial comparing the efficacy of 6 cycles versus 12 cycles temozolomide regimens in adjuvant treatment of patients with brain malignant astrocytoma

Protocol summary

Study aim

Comparison of overall survival and progression free survival between 6 cycles and 12 cycles adjuvant Temozolomide regimens in patients with brain glioblastoma and anaplastic astrocytoma

Design

This is a phase III, non-blinded, blocked randomized clinical trial. The study is conducted on 62 newly diagnosed patients with brain glioblastoma multiforme and anaplastic astrocytoma referring to the oncology clinics during March 2018 and March 2019. The patients will be randomized to 6-cycle and 12-cycle adjuvant Temozolomide groups using block randomization method (1:1).

Settings and conduct

This study will be conducted in the oncology clinic of Omid Hospital and Imam Reza Hospital, Mashhad. Blinding is not observed in this study.

Participants/Inclusion and exclusion criteria

The main inclusion criterion includes patients newly diagnosed with glioblastoma and anaplastic astrocytoma whose diagnosis is confirmed by histologic evaluation. The main exclusion criteria involve chronic renal, hepatic or cardiac failure.

Intervention groups

The patients will initially undergo surgery. Within 4 to 6 weeks after surgery, all patients will receive chemoradiation. After completion of chemoradiation, the cases will receive 12 cycles of adjuvant Temozolomide (prescribed as 150 to 200 milligram per square meter body surface per day for the first 5 days of every 28 days). In the control group, the patients will receive 6 cycles of adjuvant Temozolomide (in the same dosage).

Main outcome variables

The primary endpoints of study are overall survival and progression free survival.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160706028815N3**

Registration date: **2018-03-14, 1396/12/23**

Registration timing: **prospective**

Last update: **2018-03-14, 1396/12/23**

Update count: **0**

Registration date

2018-03-14, 1396/12/23

Registrant information

Name

Seyed Alireza Javadinia

Name of organization / entity

Department of Oncology, Omid Hospital, Mashhad
University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A single-blind, randomized, clinical trial comparing the efficacy of 6 cycles versus 12 cycles temozolomide regimens in adjuvant treatment of patients with brain malignant astrocytoma

Public title

Efficacy of two temozolomide regimens in adjuvant treatment of patients with brain malignant astrocytoma

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Newly diagnosed glioblastoma and anaplastic astrocytoma age between 18 and 70 years Karnofsky Performance Scale Index equal or more than 60 percent signed informed consent

Exclusion criteria:

chronic hepatic, renal or cardiac failure history of hematologic malignancies

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

The participants are assigned into the two intervention groups using permuted block randomization method.

Blinding (investigator's opinion)

Not blinded

Blinding description**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

Daneshgah Ave.

City

Mashhad

Province

Razavi Khorasan

Postal code

9138735499

Approval date

2017-11-01, 1396/08/10

Ethics committee reference number

IR.MUMS.fm.REC.1396.449

Health conditions studied**1****Description of health condition studied**

brain malignant astrocytoma

ICD-10 code

C71

ICD-10 code description

Malignant neoplasm of brain

Primary outcomes**1****Description**

Overall survival

Timepoint

One year after the treatment is completed

Method of measurement

Patient follow-up

2**Description**

Progression-free survival

Timepoint

12 months after the treatment is completed

Method of measurement

brain imaging and physical examination

Secondary outcomes**1****Description**

Anemia

Timepoint

Before each session of monthly chemotherapy

Method of measurement

laboratory assessment of complete blood count

2**Description**

Neutropenia

Timepoint

Before each session of monthly chemotherapy

Method of measurement

laboratory assessment of complete blood count

3

Description

Thrombocytopenia

Timepoint

Before each session of monthly chemotherapy

Method of measurement

laboratory assessment of complete blood count

4

Description

Alopecia

Timepoint

Before each session of monthly chemotherapy

Method of measurement

physical examination

5

Description

Nausea

Timepoint

Before each session of monthly chemotherapy

Method of measurement

history taking

6

Description

vomiting

Timepoint

Before each session of monthly chemotherapy

Method of measurement

history taking

Intervention groups

1

Description

Intervention group 1 (12-cycle): After completion of chemoradiation, the cases will receive 12 cycles of adjuvant Temozolomide (prescribed as 150 to 200 milligram per square meters body surface per day for the first 5 days of every 28 days).

Category

Treatment - Drugs

2

Description

Intervention group 2 (6 cycles): After completion of chemoradiation, the participants will receive 6 cycles of adjuvant Temozolomide (prescribed as 150 to 200 milligram per square meters body surface per day for the first 5 days of every 28 days).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Oncology Clinic of Omid Hospital

Full name of responsible person

Dr Kazem Anvari

Street address

Koohsangi Ave.

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2

Recruitment center**Name of recruitment center**

Oncology Clinic of Imam Reza Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Dr 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

Dr Mohammadreza Saghaei

Position

Assistant of Radiooncology

Latest degree

Medical doctor

Other areas of specialty/work

Hematology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Dr Kazem Anvari

Position

Oncologist

Latest degree

Specialist

Other areas of specialty/work

Hematology

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

Birjand University of Medical Sciences

Full name of responsible person

Mohammad Bagher Roozgar

Position

Translator

Latest degree

Master

Other areas of specialty/work

Others

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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

Deidentified Individual Participant Data Set

When the data will become available and for how long

When the study completes and for 6 months

To whom data/document is available

academic researchers

Under which criteria data/document could be used

No other criteria

From where data/document is obtainable

In the study website: [http:// yon.ir/xzDIR](http://yon.ir/xzDIR)

What processes are involved for a request to access**data/document**

registration on the study website and delivery of request

Comments