Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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)

Phone

+98 51 3802 2736

Email address

javadiniaa941@mums.ac.ir

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.
City
Mashhad
Province
Razavi Khorasan
Postal code
9176613775
Phone
+98 51 3842 6936
Email
AnvariK@mums.ac.ir

2

Recruitment center
Name of recruitment center
Oncology Clinic of Imam Reza Hospital
Full name of responsible person
Dr Kazem Anvari
Street address
Daneshgah Ave.
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 51 3842 6936
Email
AnvariK@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Mohsen Tafaghodi
Street address
Daneshgah Ave.
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 51 8384 1538
Email
tafaghodim@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
Dr Mohammadreza Saghafi
Position
Assistant of Radiooncology
Latest degree
Medical doctor
Other areas of specialty/work
Hematology
Street address
Daneshgah Ave.
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 51 3842 6936
Email
SaghafiMR951@mums.ac.ir

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
Street address
Daneshgah Ave.
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 51 3842 6936
Email
AnvariK@mums.ac.ir

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
Street address
Ghaffari Ave.
City
Birjand
Province
South Khorasan
Postal code
9717853577
Phone
+98 56 3239 5680
Email
hadirooz@gmail.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
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

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

registration on the study website and delivery of request

Comments