Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Sep 2026

Comparing the effect of neoadjuvant temozolomide before chemoradiotherapy with chemoradiotherapy followed by adjuvant temozolomide on progression free survival in patients with Glioblastoma

Protocol summary

Study aim
Discovering a method to improve progression free survival (PFS) and overall survival (OS) and cognitive complications in glioblastoma patients

Design
A randomized phase 3 clinical trial with parallel groups design of 134 patients, enrolled between October 2020 and July 2023 in a single center and followed for 2 years

Settings and conduct
Patients referred to cancer institute of Tehran Imam Khomeini hospital who have the inclusion criteria would be enrolled in this trial after being informed and randomized in either control or interventional arm. There is no possibility of blinding categorization.

Participants/Inclusion and exclusion criteria
Patients aged between 18-80 years old with histopathologic proven primary glioblastoma who are candidate for chemoradiotherapy and have acceptable performance status

Intervention groups
1.The control group would receive conventional radiotherapy and temozolomide 60 Gy radiotherapy is administered in 30 fractions over 6 weeks, concomitantly with daily doses of temozolomide 75 mg/m2 followed by 6 cycles of adjuvant temozolomide dosage 200 mg/m2 days 1-5 in a 28 days schedule 2. The intervention group receive neoadjuvant temozolomide 3 cycles followed by chemoradiotherapy and then 3 cycles of temozolomide . If clinical symptoms and signs of progression is noted radiotherapy is initiated immediately. Radiotherapy and chemotherapy are administered in the same way as for the standard treatment arm.(GTV=post-op MRI axial T1 +contrast and tumor bed, CTV=GTV+2cm smart margin) Follow up for both treatment arms is 48 months after end of treatment

Main outcome variables
Comparing progression free survival, symptoms, overall survival, clinical response due to imaging, acute reactions, cognitive function

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150929024266N5**
Registration date: **2020-11-30, 1399/09/10**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-30, 1399/09/10**
Update count: **0**

Registration date
2020-11-30, 1399/09/10

Registrant information

Name
Reza Ghalehtaki

Name of organization / entity
Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-10-06, 1399/07/15

Expected recruitment end date
2026-02-21, 1404/12/02

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effect of neoadjuvant temozolomide before chemoradiotherapy with chemoradiotherapy followed by adjuvant temozolomide on progression free survival in patients with Glioblastoma

Public title
Role of initiating treatment with temozolomide in Glioblastoma
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Histologically proven glioblastoma grade IV: GBM Age 18 - 80 years old Performance status WHO 0-2 Men and women of child bearing potential must be using adequate contraception Normal organ function, except if abnormal due to tumor involvement Patient
Exclusion criteria:
Prior chemotherapy or radiotherapy for malignant glioma Any other active malignancies within the last 5 years, except adequately treated basal or squamous cell carcinoma of the skin or carcinoma in situ Pregnancy or breast feeding Any condition (medical, social, psychological) which would prevent adequate information and follow up Platelet count (TPK) <100 x 10^9/L Hemoglobin (Hb) < 90 g/L Neutrophils: < 1.5 x 10^3/mm3 or LPK < 3.0 x 10^9/L Serum creatinine and bilirubin > 1.5 times the upper limit of normal (ULN) Alanine aminotransferase (ALT) and Aspartate aminotransferase (AST) >3 x ULN
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **134**
Randomization (investigator's opinion)
Randomized
Randomization description
patients were randomized into two groups by table of random numbers
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 Tehran University of Tehran
Street address
Keshavarz Blvd. Gharib St. Imam Khomeini Hospital Complex, Cancer institute
City
Tehran
Province
Tehran
Postal code
1419733141
Approval date
2020-10-06, 1399/07/15
Ethics committee reference number
IR.TUMS.IKHC.REC.1399.240

Health conditions studied

1

Description of health condition studied
Glioblastoma
ICD-10 code
C71
ICD-10 code description
Malignant neoplasm of brain

Primary outcomes

1

Description
Progression free survival
Timepoint
first MRI done 2-8 weeks after treatment and then within every 2-4 months interval for 3 years, every 3-6months after that, if any clinical symptoms presents follow out would take place in shorter intervals
Method of measurement
MRI Imaging changes

Secondary outcomes

1

Description
Cognitive changes
Timepoint
Before initiating treatment and then after completion of each therapeutic modality, 3 times for the control group and 4 times for the intervention group
Method of measurement
MMS (Mini-Mental State) examination test

2

Description
Hematologic complications
Timepoint
Weekly during radiotherapy and before initiation each cycle of chemotherapy
Method of measurement
Lab tests CBC

3

Description
Overall survival (OS)
Timepoint
The date of the start of treatment until the time that patients are still alive
Method of measurement
time monthly

4

Description
Renal complications
Timepoint
Weekly during radiotherapy and before initiation each cycle of chemotherapy
Method of measurement
Lab tests BUN, Cr

5

Description
Hepatic complications
Timepoint
Weekly during radiotherapy and before initiation each cycle of chemotherapy
Method of measurement
Lab tests AST, ALT, ALKP

6

Description
Neurologic defects
Timepoint
Weekly during radiotherapy and before initiation each cycle of chemotherapy
Method of measurement
Weekly history taking presence or absence of seizure, headache, FND(focal neurological defect), dexamethasone usage

Intervention groups

1

Description
Neoadjuvant temozolomide 3 cycles 200 mg/m2 days 1-5 in a 28 days schedule, followed by chemoradiotherapy , 60 Gy radiotherapy single phase is administered in 2 Gy fractions over 6 weeks (GTV=post-op MRI axial T1 +contrast tumor bed ,CTV=GTV+2cm smart margin), concomitantly with daily doses of temozolomide 75 mg/m2 and then 3 cycles of temozolomide dosage 200 mg/m2 days 1-5 in a 28 days schedule. If clinical symptoms and signs of progression is noted radiotherapy is initiated immediately.
Category
Treatment - Other

2

Description
Control group: Chemoradiotherapy, 60 Gy radiotherapy single phase is administered in 2 Gy fractions over 6 weeks (GTV=post-op MRI axial T1 +contrast and tumor bed, CTV=GTV+2cm smart margin), concomitantly with daily doses of temozolomide 75 mg/m2 6 followed by 6 cycles of temozolomide dosage 200 mg/m2 days 1-5 in a 28 days schedule.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital Complex, cancer institute
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Deputy of Research, Tehran 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
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Full name of responsible person
Reza Ghalehtaki

Position
Assisstant Professor

Latest degree
Specialist

Other areas of specialty/work
Radiotherapy

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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
Yes - There is 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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document

The study protocol (complete), Informed consent (only the blank template), Clinical study report (as the published article)

When the data will become available and for how long

6 month after the end of the study

To whom data/document is available

Only to academic individuals.

Under which criteria data/document could be used

The written request is mandatory by email emphasizing the mentioning of study conductors in case of using data

From where data/document is obtainable

By contacting this email address: rezaght@gmail.com

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

The study conductors will evaluate each request due to applicants' CV and scientific portfolio. The requests will be responded by 1 month after receiving an email.

Comments