

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

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2520

Email address

r-ghaletaki@student.tums.ac.ir

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) $< 100 \times 10^9/L$ Hemoglobin (Hb) $< 90 \text{ g/L}$ Neutrophils: $< 1.5 \times 10^3/mm^3$ or LPK $< 3.0 \times 10^9/L$ Serum creatinine and bilirubin > 1.5 times the upper limit of normal (ULN) Alanine aminotransferase (ALT) and Aspartate aminotransferase (AST) $> 3 \times \text{ULN}$

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

Reza Ghaletaki

Street address

Keshavarz Blvd. Gharib St. Imam Khomeini Hospital Complex, Cancer institute

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6119 2585

Fax

+98 21 6658 1604

Email

isnr.group@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Sahraeian

Street address

No 206, First Floor, Official Building, Medical Faculty, Poursina Street, 16th Azar Street, Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 8145 5618

Email

research@tums.ac.ir

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

Tehran University of Medical Sciences

Full name of responsible person

Reza Ghalehtaki

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Radiotherapy

Street address

Imam Khomeini Hospital Complex, Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1461833359

Phone

+98 21 6119 2585

Email

rghalehtaki@tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Reza Ghalehtaki

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Radiotherapy

Street address

Imam Khomeini Hospital Complex, Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1461833359

Phone

+98 21 6119 2585

Email

rghalehtaki@tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Department of Radiation Oncology, Tehran University of Medical Sciences

Full name of responsible person

Reza Ghalehtaki

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Radiotherapy

Street address

Department of Radiation Oncology, Cancer Institute, Imam Khomeini Hospital, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6119 2585

Fax

Email

Rezaght@gmail.com

Web page address

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