

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Sep 2026

Evaluation of chronotherapy of concomitant and adjuvant temozolamide in high grade glioma patients

Protocol summary

Study aim

Studying the effect of timing (chronotherapy) of temozolamide concomitant with radiotherapy and adjuvant on the response rate to treatment in patients with high-grade glioma referred to Shohada Tajrish and Salamat Farda hospitals in 1404-1405

Design

Randomized clinical trial, phase 1, on 60 patients, which is a random number table contrast tool

Settings and conduct

In Shohada Tajrish and Salamat Farda Hospital, all the necessary data are collected and recorded according to the history taking of physical examination and tests and MRI and are finally analyzed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: over 18 years of age with newly diagnosed grade gliomas according to the pathology report (IDH wildtype, TERT promoter mut., EGFR amp. or PTEN deletion), KPS greater than or equal to 60% and good cooperation. Pregnant and breast feeding and not cooperative patient excluded from the study

Intervention groups

Patients are randomly divided into two groups 1:1, in the first group (morning group) temozolamide is taken 1 hour before radiotherapy and before 12 am, and in the second group (evening group) temozolamide is taken 1 hour before radiotherapy and after 6pm

Main outcome variables

1 year overall survival
6 month progression free survival
6 month objective response rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241207063970N1**

Registration date: **2025-12-05, 1404/09/14**

Registration timing: **prospective**

Last update: **2025-12-05, 1404/09/14**

Update count: **0**

Registration date

2025-12-05, 1404/09/14

Registrant information

Name

Fatemeh Salari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8894 0503

Email address

f.salari1996@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-12-11, 1404/09/20

Expected recruitment end date

2026-08-23, 1405/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of chronotherapy of concomitant and adjuvant temozolamide in high grade glioma patients

Public title

Effect of time of administration of concurrent and adjuvant temozolamide in glioma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

high grade Glioma based on histopathology and IHC(Grade 3 and 4, grade2 with IDH WT, EGFR amp, TERT mut.)

Exclusion criteria:
pregnant patient Breast Feeding patient

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are divided 1:1 into two random groups in a simple and individual, and the randomization tool is a table of random numbers.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

daneshjoo ave

City

tehran

Province

Tehran

Postal code

1989934148

Approval date

2025-11-09, 1404/08/18

Ethics committee reference number

IR.SBMU.MSP.REC.1404.455

Health conditions studied

1

Description of health condition studied

Glioma, glioblastoma

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

objective response rate, progression free survival

Timepoint

6 month after treatment completion

Method of measurement

MRI and response rate based on RECIST criteria

Secondary outcomes

1

Description

overall survival

Timepoint

1 year

Method of measurement

Contact the patient

Intervention groups

1

Description

AM (Taking temozolamide before 12:00 AM, either simultaneously with radiotherapy (with an interval of 1 hour before radiotherapy) or as an adjuvant)

Category

Treatment - Other

2

Description

PM (Taking temozolamide after 6 pm, either simultaneously with radiotherapy (with an interval of 1 hour before radiotherapy) or as an adjuvant)

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tajrish Martyrs Hospital, Salamat Farda Hospital

Full name of responsible person

Fatemeh Salari

Street address

shahrdari ave, qods square, tehran town

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Phone

+98 21 25719

Email

pr-shohada@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Shahid Aarabi Ave, Shahid Chamran Blvd, tehran town

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1985717434

Phone

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Fatemeh Salari

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Radiotherapy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Phone

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Email

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

All participant data can be shared after de-identifying individuals.

When the data will become available and for how long

Access period starts 6 months after results are published.

To whom data/document is available

It will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Access is open for research purposes.

From where data/document is obtainable

Correspondence via email f.salari1996@gmail.com

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

After submitting the request and clarifying the applicant's intentions, if for research purposes, the information will be provided to the applicant via email, while maintaining ethical standards.

Comments