Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison the efficacy of dimethyl fumarate administration vs placebo on neurosurgical brain induced injury measured by S100 beta protein concentration and performance (Karnofsky scale), in glioblastoma multiform patient operated in Shariati Hospital from 2018 to 2021

Protocol summary

Study aim
Determination and comparison of the efficacy of dimethyl fumarate and placebo on the extent of surgical brain injury measured by changes in S100 protein concentration and functional index of patients with glioblastoma multiforme measured by Karnowski scale

Design
A randomized, parallel controlled, triple-blinded clinical trial

Settings and conduct
Seventy-two patients with primary GBM referred to Shariati Hospital, Tehran, from 2018 to 2021 were randomly divided into two groups: 1-Dimethyl fumarate recipient 2-placebo group. Patients in the intervention and placebo groups will receive drug or placebo surgery for 7 days. The mean score of karnofski at the time of study entry and again on the 30th day of surgery was determined in both groups. S100β levels in peripheral blood will be measured before and 48 24 24 hours after surgery using a special ELISA kit. The surgeon, patient, and statistical analyst will be blind to this.

Participants/Inclusion and exclusion criteria
Seventy-two patients with primary GBM referred to Shariati Hospital in Tehran during 2018-2021who underwent surgery will be enrolled. Patients with a previous history of GBM, medical disorders, pregnancy or lactation and immunodeficiency will also not be included in the study.

Intervention groups
Intervention group: Routine treatment (including phenytoin, dexamethasone, and cefazolin) plus three dimethyl fumarate tablets (240 mg daily) one week before surgery Placebo group: Routine treatment (including phenytoin, dexamethasone, and cefazolin) plus three placebo tablets and non-mainstream drugs (eg., preservatives agents) will be received one week before surgery.

Main outcome variables
1. Karnowski score on the baseline and 30 days after surgery 2. S100 protein levels before and 48 hours after surgery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200226046624N1**
Registration date: **2020-03-07, 1398/12/17**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-07, 1398/12/17**
Update count: **0**

Registration date
2020-03-07, 1398/12/17

Registrant information

Name
Alireza Khoshnevisan

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8490 2380

Email address
akhoshnevisan@tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-03-21, 1397/01/01

Expected recruitment end date
2022-03-11, 1400/12/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison the efficacy of dimethyl fumarate administration vs placebo on neurosurgical brain induced injury measured by S100 beta protein concentration and performance (Karnofsky scale), in glioblastoma multiform patient operated in Shariati Hospital from 2018 to 2021

Public title
Efficacy of dimethyl fumarate administration vs placebo on neurosurgical brain induced injury measured by S100 beta protein concentration and performance (Karnofsky scale) among glioblastoma multiform patient
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Newly diagnosed monofocal GBM with strong evidence of MRI T1+GAD and histology confirmed after surgery by an identical pathologist (WHO grade IV). Patients ≥ 18 years Adequate activity of liver, kidney, bone marrow and coagulation system Contraceptive drug use Signing and obtaining informed consent for inclusion in the study
Exclusion criteria:
History of acute or chronic disease with poor prognosis, autoimmune diseases, immunodeficiency with a history of previous cancer Any infection in the last 2 weeks that has caused hospitalization or treatment with antibiotics or antivirals Drug sensitivity to temozolomide, dimethyl fumarate, phenytoin, dexamethasone, and cefazolin A history of coagulating or bleeding disorders Previous GBM Pregnancy or lactation High liver enzymes (over twice the normal) and proteinuria (more than 150 mg daily) Patients with diagnosis mixed tumor after surgery based on their tumor pathology report. Initial WBC less than 3500 or lymphopenia below 500 A history of immunological disorders (such as cancer, lymphoma, positive serologic testing, HIV or viral hepatitis) over the past 6 months Patients with poorly compliance and did not use the drug correctly before surgery. Tumor metastasis Other brain and non-brain tumors History of significant head trauma in the past three months Indication of GBM emergency surgery Psychosis and cognitive impairment A history of disability from other neurodegenerative diseases such as CVA and hemiparesis MRI contraindications
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
The random listing of patients in groups is based on random blocks of 4, 6, and 8 and is centrally performed by the concealment officer and the person performing the randomization of each related group that unaware of intervention.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Patients in both groups receive routine drug therapy, and the patient will be prescribed medications as before. Routine drug therapy includes phenytoin, dexamethasone, and cefazolin. Patients treated with dimethyl fumarate will receive three pills (240 mg/day) daily from one week before surgery in addition to routine treatments. The control group will go through the same procedure as the treatment group, with the exception of taking three dimethyl fumarate tablets per day that will not be prescribed in this group, and placebo tablets of the same form and other non-mainstream drugs (e.g., preservatives) will be received. The surgeon, patient, and statistical analyst will be blind to this procedure.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Tehran University of Medical Sciences
Street address
Vice Chancellor for Research and Technology, Sixth Floor, Qods Ave., Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1416753955
Approval date
2019-07-17, 1398/04/26
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1398.344

Health conditions studied

1

Description of health condition studied
Gliobalstom multiforme
ICD-10 code
C71.9
ICD-10 code description
Malignant neoplasm of brain, unspecified

Primary outcomes

1

Description
Performance status
Timepoint
Before and 30 day after surgery
Method of measurement
Karnofsky score

2

Description
S100 beta protein
Timepoint
Before and 48 hours after surgery
Method of measurement
ELISA kit

Secondary outcomes

1

Description
Drug adverse effects
Timepoint
During study period
Method of measurement
Physical exam and patient reports

Intervention groups

1

Description
Intervention group: Routine treatment (including phenytoin, dexamethasone and cefazolin) plus three dimethyl fumarate tablets (240 mg daily) one week before surgery
Category
Treatment - Drugs

2

Description
Control group: Routine treatment (including phenytoin, dexamethasone and cefazolin) plus three placebo tablets and non-mainstream drugs (such as the same preservatives) will be received one week before surgery.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati Hospital
Full name of responsible person
Alireza Khoshnevisan
Street address
North Kargar Street, Jalal Al Ahmad Road
City
Tehran
Province
Tehran
Postal code
1411713135
Phone
+98 21 8490 1000
Email
akhoshnevisan@tums.ac.ir
Web page address
http://shariati.tums.ac.ir/Home

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Alireza Khoshnevisan
Street address
Shariati Hospital Research and Treatment Center, North Kargar Street, Jalal Al Ahmad Road
City
Tehran
Province
Tehran
Postal code
1411713135
Phone
+98 21 8490 1000
Email
akhoshnevisan@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
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

Niayesh Mohebbi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

Street address

Shariati Hospial, Jalal-e-Al-Ahmad Ave

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8490 2380

Fax

Email

nmohebbi@tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Alireza Khoshnevisan

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

Street address

Shariati Hospial, Jalal-e-Al-Ahmad Ave

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8490 2380

Fax

Email

akhoshnevisan@tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Milad Shafizadeh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Neurosurgery

Street address

Shariati Hospial, Jalal-e-Al-Ahmad Ave

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8490 2380

Fax

Email

milad_shafizadeh@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

Not applicable

Title and more details about the data/document

The clinical report of the study will be analyzed and published after the end of the study

When the data will become available and for how long

Start of access period 6 months after publishing results

To whom data/document is available

All the researcher in medical fields

Under which criteria data/document could be used

For the purpose of research use and with the written consent of the corresponding author

From where data/document is obtainable

Corresponding author

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

The official request must be sent to the coresponding

author by email or fax.

Comments