

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

A Clinical trial to assess the effects of short-term administration of cyclosporine on survival of patients with glioblastoma multiforme tumor surgery

Protocol summary

Study aim

Evaluation of the efficacy and side effects of cyclosporine in the treatment of patients with glioblastoma multiforme

Design

Two arm parallel groups, randomised trial with blinded postoperative care and outcome assessment, phase 2-3 on 99 patients. Computer sequencing was used for randomization.

Settings and conduct

Patients referred to Shariati Hospital in Tehran, who were definitively diagnosed with glioblastoma based on frozen section surgery, were randomly allocated to the study. Patients then received envelopes labeled A and B containing the cyclosporine or placebo. In this study, patients, researchers and analyzers were not aware of the individuals assigned to the study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Age over 18 years 2. Definitive diagnosis of glioblastoma tumor Exclusion criteria: 1. History of previous brain tumor surgery 2. Receive previous chemotherapy 3. Pregnancy 4. Breastfeeding 5. Immune defect 6. Active infection 7. Hepatitis

Intervention groups

Intervention group: Injectable cyclosporine (2.5 mg / kg for 2 hours for the patient and then infused at a dose of 5 mg / kg per day for 72 hours) Control group: receiving placebo

Main outcome variables

Overall survival Progression-free survival One year survival Performanc status (Karnovsky score)

General information

Reason for update

Regarding the completion of the study, some conditions related to the design of the study were updated. 1. The study was conducted as triple blind. 2. In addition to

standard treatment, the control group also received a placebo.

Acronym

IRCT registration information

IRCT registration number: **IRCT201512028612N3**

Registration date: **2016-01-22, 1394/11/02**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-18, 1400/10/28**

Update count: **1**

Registration date

2016-01-22, 1394/11/02

Registrant information

Name

Amir Sarayani

Name of organization / entity

Research Center for Rational Use of Drugs

Country

Iran (Islamic Republic of)

Phone

+98 21 8881 4157

Email address

a-sarayanib@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Science, Shariati Hospital

Expected recruitment start date

2014-07-23, 1393/05/01

Expected recruitment end date

2016-04-20, 1395/02/01

Actual recruitment start date

2014-07-23, 1393/05/01

Actual recruitment end date

2017-04-21, 1396/02/01

Trial completion date

Scientific title

A Clinical trial to assess the effects of short-term administration of cyclosporine on survival of patients with glioblastoma multiforme tumor surgery

Public title

Effect of an immuno-suppressive medication (cyclosporine) on brain tumor patients survival

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 18 years No history of surgery and/or previous chemotherapy Confirmed diagnosis of glioblastoma

Exclusion criteria:**Age**

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

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

Sample size

Target sample size: **40**

Actual sample size reached: **99**

Randomization (investigator's opinion)

Randomized

Randomization description

A computer-generated sequence with a block size of 4 patients was used for randomization. The patients were assigned consecutive numbers based on their order of enrolment in the study. Thus, unblinded pharmacists who were otherwise uninvolved in study conduct obtained randomized treatment assignments and managed study treatment

Blinding (investigator's opinion)

Triple blinded

Blinding description

Patients were allocated to group A and B and received envelopes labeled A and B that contained Cyclosporine or placebo after surgery. Hence, neither the patients nor all investigators were aware of the drug contents and group allocation.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tehran University of Medical Sciences, Ethics Committee

Street address

Ghods junction, Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1411713135

Approval date

2015-06-17, 1394/03/27

Ethics committee reference number

IR.TUMS.REC.1394.76

Health conditions studied**1****Description of health condition studied**

glioblastoma multiform

ICD-10 code

C71.9

ICD-10 code description

Malignant neoplasm of brain/unspecified

Primary outcomes**1****Description**

Performance Status (Survival)

Timepoint

measured every 2 months after recruitment up to one year

Method of measurement

Karnofsky Performance Status Scale

Secondary outcomes

empty

Intervention groups**1****Description**

Infusion of 2.5 mg/kg cyclosporine over first 2 hours post operation and will be continued with the dose of 5mg/kg /day for 72 hours

Category

Treatment - Drugs

2**Description**

control group: routine care of post op GBM patients
Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shariati Hospital
Full name of responsible person
Dr Khoshnevisan
Street address
جلال آل احمد
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1411713135
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akhoshnevisan@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr khoshnevisan
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Email
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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
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 Science
Full name of responsible person
Dr Farzaneh
Position
MD
Latest degree
Specialist
Other areas of specialty/work
Neurosurgery
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Fax**Email**

ff1353@yahoo.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

Publish as scientific article

When the data will become available and for how long

from 2021

To whom data/document is available

Researchers

Under which criteria data/document could be used

To design future studies

From where data/document is obtainable

Dr. Alireza Khoshnevisan

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

Formal request to principal researcher of study

Comments