Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Aug 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 alocated 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

2020-03-20, 1399/01/01

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-suppresive 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 chemoteraphy Confirmed diagnosis of gliobalstoma

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

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8490 1000

Email

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

Street address

Shariati Hospital

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 Science

Full name of responsible person

Dr Farzaneh

Position

MD

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

Street address

Shariati Hospital

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8490 1000

Fax

Email

ff1353@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Khoshnevisan

Position

MD

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

Street address

Shariati Hospital

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8490 1000

Fax

Email

akhoshnevisan@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr Farzaneh

Position
MD

Latest degree
Specialist

Other areas of specialty/work
Neurosurgery

Street address
Shariati Hospital

City
Tehran

Province
Tehran

Postal code
1411713135

Phone
+98 21 8490 1000

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 scintifice 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