

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Intracerebral Administration of Allogeneic/Autologous Mesenchymal Stem Cells as HSV-TK Gene Vehicle for Treatment of Glioblastoma: Safety and Feasibility Assessment

Protocol summary

Study aim

Evaluation of safety and feasibility of using allogeneic/autologous mesenchymal stem cells containing lentivirus carrying thymidine kinase gene in patients with glioblastoma multiforme.

Design

Uncontrolled phase 1 clinical trial in 5 patients.

Settings and conduct

Five patients with glioblastoma confirmed by two pathologists will be examined in this study. This study does not have a control group and randomization. Patients will be examined every three months until tumor recurrence and death. The study site will be Shohadaye Tajrish Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Karnofsky performance status > 70. Adequate hematological function (an absolute neutrophil count > 1500/ μ l and platelet count > 125000/mm³). Adequate renal function (creatinine < 1.5 times the normal). Adequate hepatic function (aspartate aminotransferase and bilirubin < 1.5 times the normal). Patients who fill informed consent. Exclusion criteria: Significant vascular disease. History of recurrent thromboembolism. Prior history of hypertensive crisis or hypertensive encephalopathy. Gastrointestinal fistula or perforation. History of an intraabdominal or intracranial abscess within 6 months. Serious non-healing wound, ulcer and bone fracture.

Intervention groups

Intervention group: This group undergoes gene therapy along with standard treatment (chemotherapy and radiotherapy). Then 5×10^5 mesenchymal stem cells infected with lentivirus carrying the Thymidine Kinase gene are injected into the tumor site using stereotactic injection. After cell injection, the Ganciclovir drug administration continues for a total of 28 doses over 14 days.

Main outcome variables

Overall survival; progression-free survival.

General information

Reason for update

Given the ease of availability, isolation, and preparation process as well as less associated morbidity for patients, allogeneic cell source was also added to the study. This change was made in the study title.

Acronym

IRCT registration information

IRCT registration number: **IRCT20200502047277N2**

Registration date: **2020-10-08, 1399/07/17**

Registration timing: **retrospective**

Last update: **2022-11-05, 1401/08/14**

Update count: **1**

Registration date

2020-10-08, 1399/07/17

Registrant information

Name

saeed oraee yazdani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 25719

Email address

saeed_o_yazdani@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-11, 1396/09/20

Expected recruitment end date

2020-09-05, 1399/06/15
Actual recruitment start date
 2018-02-04, 1396/11/15
Actual recruitment end date
 2020-09-05, 1399/06/15
Trial completion date
 2020-09-05, 1399/06/15

Scientific title
 Intracerebral Administration of Allogeneic/Autologous Mesenchymal Stem Cells as HSV-TK Gene Vehicle for Treatment of Glioblastoma: Safety and Feasibility Assessment

Public title
 Evaluation of the safety and feasibility of stem cell-mediated gene therapy in the treatment of glioblastoma

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Karnofsky performance status > 70. Adequate hematological function (an absolute neutrophil count > 1500/ μ l and platelet count > 125000/mm³). Adequate renal function (creatinine < 1.5 times the normal). Adequate hepatic function (aspartate aminotransferase and bilirubin < 1.5 times the normal). Patient who fill informed consent.
Exclusion criteria:
 Significant vascular disease. History of recurrent thromboembolism. Prior history of hypertensive crisis or hypertensive encephalopathy. Gastrointestinal fistula or perforation. History of intraabdominal or intracranial abscess within 6 months. Serious non healing wound, ulcer and bone fracture.

Age
 No age limit

Gender
 Both

Phase
 1

Groups that have been masked
No information

Sample size
 Target sample size: **8**
 Actual sample size reached: **5**

Randomization (investigator's opinion)
 N/A

Randomization description
Blinding (investigator's opinion)
 Not blinded

Blinding description
Placebo
 Not used

Assignment
 Single

Other design features

Secondary Ids
 empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Vice-Chancellor in Research Affairs - Shahid Beheshti University of Medical Sciences

Street address

7th Floor, Building Number. 2, Shahid Beheshti University of Medical Sciences, Arabi Avenue, Daneshjoo Boulevard, Velenjak, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1989934148

Approval date

2017-06-07, 1396/03/17

Ethics committee reference number

IR.SBMU.REC.1396.224

Health conditions studied

1

Description of health condition studied

Glioma grade 4

ICD-10 code

C71

ICD-10 code description

Malignant neoplasm of brain

Primary outcomes

1

Description

Overall survival (OS) of patients

Timepoint

Before treatment and every three months until the patient's death

Method of measurement

The time from treatment initiation until patient's death

2

Description

Radiological progression free survival (PFS) of patients

Timepoint

Before treatment and every three months until the disease recurrence

Method of measurement

The time from treatment initiation until disease progression or worsening

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group undergoes gene therapy along with standard treatment (chemotherapy and radiotherapy). Then 5×10^5 mesenchymal stem cells infected with lentivirus carrying the Thymidine Kinase gene are injected into the tumor site through stereotactic injection. After cell injection, the Ganciclovir drug administration continues for a total of 28 doses over 14 days.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Tajrish Hospital

Full name of responsible person

Saeed Oraee Yazdani

Street address

Shohadaye Tajrish hospital, Tajrish Square.

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1989934148

Phone

+98 21 25719

Email

Saeed_o_yazdani@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

7th Floor, Building Number. 2, Shahid Beheshti University of Medical Sciences, Arabi Avenue, Daneshjoo Boulevard, Velenjak, Tehran, Iran.

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Mpajouhesh@sbmu.ac.ir

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

Saeed Oraee Yazdani

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

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Shohadaye Tajrish Hospital, Tajrish Ave.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Masoud Soleimani

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Cell Therapy and Hematology

Street address

Tarbiat Modares University, Jalal AleAhmad Highway

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1411713116
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Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mohammadhosein Akhlaghpasand
Position
Research Associate
Latest degree
Medical doctor
Other areas of specialty/work
Neuroscience
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akhlaghpasandm@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

through email request

When the data will become available and for how long

12 month

To whom data/document is available

Principal investigator of other clinical trials

Under which criteria data/document could be used

official request

From where data/document is obtainable

direct request to email

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

evaluation of the validity of the applicant

Comments