Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jun 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/µl 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/µl 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 Scie

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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Saeed Oraee Yazdani

Position
Assisstant professor

Latest degree
Specialist

Other areas of specialty/work
Neurosurgery

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Person responsible for scientific inquiries

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Professor

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Ph.D.

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Cell Therapy and Hematology

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Person responsible for updating data

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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