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

Protocol summary

Study aim
Evaluation of safety and feasibility of using bone marrow 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). From this group of patients, bone marrow stem cells are isolated and brain tumor resection is performed on them. Then 5 x 10^5 mesenchymal stem cells infected with lentivirus carrying the Thymidine Kinase gene are injected into the evacuated tumor site under the guidance of a brain navigation device. 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

Acronym

IRCT registration information
IRCT registration number: IRCT20200502047277N2
Registration date: 2020-10-08, 1399/07/17
Registration timing: retrospective

Last update: 2020-10-08, 1399/07/17
Update count: 0

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 Autologous Mesenchymal Stem Cells as HSV-TK Gene Vehicle to 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
Not blinded

Blinding (investigator's opinion)
Not blinded

Blinding description
Not used

Placebo
Not used

Assignment
Single

Other design features
empty

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, Arbi 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
Gioma 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
empty
Intervention group: This group undergoes gene therapy along with standard treatment (chemotherapy and radiotherapy). From this group of patients, bone marrow stem cells are isolated and brain tumor resection is performed on them. Then 5×10^5 mesenchymal stem cells infected with lentivirus carrying the Thymidine Kinase gene are injected into the evacuated tumor site under the guidance of a brain navigation device. After cell injection, the Ganciclovir drug administration continues for a total of 28 doses over 14 days.

Category
- Treatment - Other

Recruitment centers

Recruitment center
- Name of recruitment center: Shohadaye Tajrish Hospital
- Full name of responsible person: Saeed Oraee Yazdani
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- City: Tehran
- Province: Tehran
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Sponsors / Funding sources

Sponsor
- Name of organization / entity: Shahid Beheshti University of Medical Sciences
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- Grant name

Person responsible for general inquiries

Contact
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- Name of organization / entity: Tarbiat Modares University
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Person responsible for updating data

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Latest degree
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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