Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Local Carcinoembryonic antigen-expressing oncolytic measles virus for residual or recurrent glioblastoma: a phase1 and 2 study

Protocol summary

Study aim
To determine the effect of using topical Carcinoembryonic antigen-expressing oncolytic measles virus (MV-CEA) for the treatment of residual or recurrent glioblastoma in terms of the maximum dose of the virus and its side effects, and its impact on the radiological and clinical outcome of patients.

Design
The study protocol for Phase I is a 3+3 design. The Phase I portion includes an escalating dose schedule of MV virus. The highest dose tested in Phase I is used in Phase II. In phase 2 of this study, the clinical and radiological outcome of GBM patients with relapsed or residual tumor will be evaluated.

Settings and conduct
This study is being conducted at Imam Hussein Hospital and patients with glioblastoma multiforme tumor and whose inclusion and exclusion criteria have been examined will be studied in two phases of the study. In phase one, the maximum tolerated dose and possible side effects will be examined, and in phase two, the effectiveness will be evaluated based on clinical and radiological outcomes.

Participants/Inclusion and exclusion criteria
Patients over 18 years of age with glioblastoma multiforme who have had recurrence or residual tumor after surgery and adjuvant therapies.

Intervention groups
This study investigates the effect of Carcinoembryonic antigen-expressing oncolytic measles virus (MV-CEA) in the treatment of glioblastoma multiforme. For all cases, the virus is inoculated into the tumor site during surgery.

Main outcome variables
Survival rate, radiological enhancement

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210712051848N3**
Registration date: **2025-01-19, 1403/10/30**
Registration timing: **registered_while_recruiting**

Last update: **2025-01-19, 1403/10/30**
Update count: **0**

Registration date
2025-01-19, 1403/10/30

Registrant information

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Hamid Reza Khayat Kashani

Name of organization / entity

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2025-01-19, 1403/10/30

Expected recruitment end date
2027-01-20, 1405/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Local Carcinoembryonic antigen-expressing oncolytic measles virus for residual or recurrent glioblastoma: a phase1 and 2 study

Public title
Carcinoembryonic antigen-expressing oncolytic measles virus for the treatment of glioblastoma
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Histologically confirmed recurrent or residual glioblastoma that is progressive despite prior or ongoing radiation therapy. An enhanced lesion measuring one centimeter or more in diameter on MRI with contrast Karnofsky Performance Scale (KPS) >=70% Age greater than or equal to 18 years Willing to use effective contraception for at least 6 months after oncolytic virus administration Expected survival greater than 3 months Absolute neutrophil count (ANC) >= 1500/uL Platelets (PLT) >= 100,000/uL Total bilirubin =< 1.5 times the upper limit of normal (ULN) Aspartate aminotransferase (AST) =< 2 x ULN Creatinine =< 2.0 x ULN Prothrombin time (PT) and activated partial thromboplastin time (aPTT) =< 1.3 x ULN Anti-measles viral immunity demonstrated by immunoglobulin (IgG) and anti-measles antibody levels >= 1.1 EU/ml, determined by enzyme-linked immunosorbent assay Normal serum CEA level (<3 ng/mL) at baseline Negative serum pregnancy test performed <= 7 days prior to study entry (only for women of childbearing age) Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 or 2 Informed consent to participate in the study
Exclusion criteria:
Multiple (more than one) intracranial malignant glioma lesions Documented extracranial metastases Laboratory test values for CBC, platelets, clinical chemistry, liver and kidney function tests outside the protocol-specified limits Chemotherapy, cytotoxic, or immunotherapy within 6 weeks prior to oncolytic virus administration Any contraindications for MRI, such as pacemakers, infusion pumps, etc. Surgery within 4 weeks before oncolytic virus administration Pregnant or breastfeeding women Active infection = < 5 days prior to study start History of tuberculosis or history of positive purine protein derivative (PPD) tests Chemotherapy =< 4 weeks prior to study start (6 weeks for nitrosourea-based chemotherapy) Immunotherapy =< 4 weeks before study start Biological therapy =< 4 weeks before study start Bevacizumab =< 12 weeks prior to study start Administration of non-cytotoxic antitumor drugs, i.e. small molecule cell cycle inhibitors, less than 2 weeks before the start of the study Radiation therapy =< 6 weeks prior to study start Failure to fully recover from the acute and reversible effects of previous chemotherapy, regardless of the time interval since the last treatment. Inadequate seizure control History of organ transplantation History of chronic hepatitis B or American Society of Anaesthesiology (ASA) Class 3 or 4 Allergy to measles vaccine or history of severe reaction to previous measles vaccination History of any of the following: HIV, use of other investigational agents or vaccination within 30 days; encephalitis, multiple sclerosis or other CNS infections; previous gene transfer therapy or previous treatment with a cytolytic virus of any type
Age
From **18 years** old
Gender
Both

Phase
1-2
Groups that have been masked
No information
Sample size
Target sample size: **43**
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
Shahid Chamran Highway, Yemen Street, Shahid Arabi Street
City
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Tehran
Postal code
1985717443
Approval date
2025-01-12, 1403/10/23
Ethics committee reference number
IR.SBMU.RETECH.REC.1403.663

Health conditions studied

1

Description of health condition studied
Brain Tumor
ICD-10 code
C71
ICD-10 code description
Malignant neoplasm of brain

Primary outcomes

1

Description
Patient survival time
Timepoint
Every month as long as the patient survivesپ
Method of measurement
Questionnaire

Secondary outcomes

1

Description
Change in the volume of the enhanced area in MRI
Timepoint
ماهانه تا زمان زنده ماندن بیمار
Method of measurement
Review of MRI images

Intervention groups

1

Description
Intervention group: Local inoculation of oncolytic virus at the tumor site
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hussein Hospital
Full name of responsible person
Hamid Reza Khayat Kashani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
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
Hamid Reza Khayat Kashani
Position
Associate professor
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Specialist
Other areas of specialty/work
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Person responsible for updating data

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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
All patient data, including clinical characteristics and radiological data, will be published after de-identification in an attachment to the publication of the article related to the project.
When the data will become available and for how long
At the time of publication of the relevant article
To whom data/document is available
Anyone who wants to can have access to the data.
Under which criteria data/document could be used
Data is publicly available.
From where data/document is obtainable
Data are available in the appendix of the relevant article.
What processes are involved for a request to access data/document
The data is publicly available in the appendix of the relevant article in the journal that publishes it.
Comments