

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Aug 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

Name

Hamid Reza Khayat Kashani

Name of organization / entity

Country

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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) $\geq 70\%$ 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) $\geq 1500/\mu\text{L}$ Platelets (PLT) $\geq 100,000/\mu\text{L}$ Total bilirubin ≤ 1.5 times the upper limit of normal (ULN) Aspartate aminotransferase (AST) $\leq 2 \times \text{ULN}$ Creatinine $\leq 2.0 \times \text{ULN}$ Prothrombin time (PT) and activated partial thromboplastin time (aPTT) $\leq 1.3 \times \text{ULN}$ Anti-measles viral immunity demonstrated by immunoglobulin (IgG) and anti-measles antibody levels $\geq 1.1 \text{ EU/ml}$, determined by enzyme-linked immunosorbent assay Normal serum CEA level ($< 3 \text{ ng/mL}$) 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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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

Afshin Zarghi

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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

Latest degree

Specialist

Other areas of specialty/work

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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