

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Investigation the effect of transcranial electrical stimulation on GBM tumor growth and depression

#### Protocol summary

Tumor size changes, depression amount changes

#### Study aim

The purpose of this clinical trial is to investigate transcranial electrical stimulation on glioblastoma brain tumor growth and depression caused by it.

#### Design

A controlled, parallel-group, without blinding, randomized, clinical trial on 54 patients. Simple individual randomization with a sealed previously prepared envelope was used for randomization.

#### Settings and conduct

For the first intervention group, intermittent tECS is applied in the area where the glioblastoma brain tumor is located with a maximum current of 2 milliamps and a maximum voltage of 18 volts (during 20 consecutive sessions of 12 hours). For the second intervention group, without applying electric current, it is performed with the same protocol. All three treatment groups receive routine chemotherapy. At the beginning of the study (before the start of the intervention) and at the end of the study (45 days after the start of the intervention), MRI images will be taken from all patients with the injection of Hamilton Depression Questionnaire and Beck Depression Questionnaire. Location: National Brain Mapping Laboratory - Tarbiat Modares University - Lohman Hakim Hospital

#### Participants/Inclusion and exclusion criteria

Eligibility Criteria: Patients aged between 10 years and 75 years  
Patients with recurrent glioblastoma tumor  
Exclusion criteria: People with systemic diseases  
Patient's non-cooperation

#### Intervention groups

18 patients simultaneously undergoing standard chemotherapy treatment  
Another 18 patients are simultaneously treated with standard chemotherapy and alternating electric current  
18 other patients are simultaneously treated with standard chemotherapy and alternating electric current of virtual feedback (without applying electrical stimulation).

#### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191208045665N2**

Registration date: **2023-01-11, 1401/10/21**

Registration timing: **prospective**

Last update: **2023-01-11, 1401/10/21**

Update count: **0**

##### Registration date

2023-01-11, 1401/10/21

##### Registrant information

##### Name

Mohammad Rostami

##### Name of organization / entity

The University of Tarbiat Modares

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8288 3904

##### Email address

m-rostami@modares.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-01-21, 1401/11/01

##### Expected recruitment end date

2023-02-20, 1401/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Investigation the effect of transcranial electrical stimulation on GBM tumor growth and depression

**Public title**

The effect of transcranial electrical stimulation on brain tumor growth and depression caused by it trial

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age between 10-75 years old Patients with recurrent Glioblastoma Brain tumor

**Exclusion criteria:**

People with systemic diseases Patient's non-cooperation

**Age**

From **10 years** old to **75 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **54**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple individual randomization with a sealed previously prepared envelope

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Iran University of Medical Sciences

**Street address**

Simulation Systems Laboratory, Faculty of Electrical Engineering, Tarbiat Modares University, Nasr Bridge, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1411713116

**Approval date**

2022-12-28, 1401/10/07

**Ethics committee reference number**

IR.IUMS.REC.1401.739

**Health conditions studied****1****Description of health condition studied**

Glioblastoma Brain Tumor

**ICD-10 code**

C71.9

**ICD-10 code description**

Malignant neoplasm of brain, unspecified

**Primary outcomes****1****Description**

Depression score in Hamilton questionnaire

**Timepoint**

At the beginning of the study (before the start of the intervention) and at the end of the study (45 days after the start of the intervention)

**Method of measurement**

Depression Hamilton Scale

**2****Description**

Tumor size in MRI with contrast

**Timepoint**

At the beginning of the study (before the start of the intervention) and at the end of the study (45 days after the start of the intervention)

**Method of measurement**

MRI imaging

**3****Description**

Depression score in Beck questionnaire

**Timepoint**

At the beginning of the study (before the start of the intervention) and at the end of the study (45 days after the start of the intervention)

**Method of measurement**

Beck Depression Inventory

**Secondary outcomes**

empty

**Intervention groups****1****Description**

First intervention group: Simultaneously under the standard treatment of chemotherapy and alternating electric current - ). Intermittent tECS is used where the glioblastoma brain tumor is located with a maximum current of 2 milliamps and a maximum voltage of 18 volts (during 20 consecutive sessions of 12 hours). They receive standard chemotherapy treatment according to the treatment protocol.

**Category**

Treatment - Other

**2**

**Description**

Second intervention group: Simultaneously under the standard treatment of chemotherapy and alternating electric current of virtual feedback - ). Intermittent tECS is used where the glioblastoma brain tumor is located without applying electrical stimulation (during 20 consecutive sessions of 12 hours). They receive standard chemotherapy treatment according to the treatment protocol.

**Category**

Treatment - Other

**3**

**Description**

Control group: Simultaneously under standard chemotherapy treatment. They receive standard chemotherapy treatment according to the treatment protocol.

**Category**

Treatment - Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Loghman Hakim hospital

**Full name of responsible person**

Guive Sharifi

**Street address**

Special Street, Lashkar Crossroads, Tehran

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1333635445

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loghman.hospital@sbm.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Tarbiat Modares University

**Full name of responsible person**

Mohammad Rostami

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M-Rostami@modares.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Mohammad Rostami

**Proportion provided by this source**

100

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

Persons

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Tarbiat Modares University

**Full name of responsible person**

Mohammad Rostami

**Position**

Project manager of simulation systems laboratory of Tarbiat Modares University

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Neuroscience

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## Person responsible for scientific inquiries

**Contact**

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Tarbiat Modarres University

**Full name of responsible person**

Mohammad Rostami

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## Person responsible for updating data

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Tarbiat Modarres University

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Mohammad Rostami

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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**

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

**Statistical Analysis Plan**

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

**Informed Consent Form**

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

**Clinical Study Report**

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

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable