Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigation the effect of transcranial electrical stimulation on GBM tumor growthand depression

Protocol summary

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 - Loghman 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

Tumor size changes, depression amount changes

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 growthand 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

City

Tehran

Province

Tehran

Postal code

1333635445

Phone

+98 21 5541 9005

Email

loghman.hospital@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Mohammad Rostami

Street address

Simulator Systems Laboratory - Faculty of Electrical Engineering - Tarbiat Modares University- Nasr Bridge

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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

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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