

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

The evaluation of the effectiveness of adjunctive application of transcranial direct current stimulation (tDCS) in the management of patients with super-refractory convulsive status epilepticus

Protocol summary

Study aim

The effectiveness of adjunctive application of transcranial direct current stimulation (tDCS) in the management of patients with super-refractory convulsive status epilepticus

Design

An open label clinical trial as a pilot study with control group and non-randomized parallel intervention group on 20 patient

Settings and conduct

Patients with super-refractory convulsive status epilepticus admitted to hospitals affiliated with Shiraz University of Medical Sciences in the intervention group, as mentioned, will be intervened, whereas patients in the control group will get just standard therapies. The ECG is performed on all patients in the intervention group 30 minutes before and 30 minutes after the intervention. However, in the control group, just one ECG will be performed at the final.

Participants/Inclusion and exclusion criteria

IC: patients with a diagnosis of tonic-clonic super-refractory convulsive status epilepticus EC: Patients with major psychiatric diseases, drug addiction, Seizures are caused by metabolic abnormalities, pregnancy, skull defects,

Intervention groups

Patients with super-refractory convulsive status epilepticus who receive only conventional therapies as a control group. Intervention group: Patients with super-refractory status epilepticus who have not responded to standard therapies should be treated with tCSD, which entails implanting the appropriate leads in the T5 and F4 areas and stimulating them once for 20 minutes at a current of 2 mA. For 20 minutes, they will each receive the same amount of electrical stimulation in regions T6 and F3 on the opposite side.

Main outcome variables

Reduction or elimination of convulsive movements in patients; electroencephalogram's background wave; Improving patients' epileptiform discharges ; Improving patients' level of consciousness; Reducing the hospitalization rate of patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200517047483N2**

Registration date: **2022-03-16, 1400/12/25**

Registration timing: **registered_while_recruiting**

Last update: **2022-03-16, 1400/12/25**

Update count: **0**

Registration date

2022-03-16, 1400/12/25

Registrant information

Name

Mahtab Rostamhosseinkhani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3820 6907

Email address

mahtabrostami85@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-20, 1400/12/01

Expected recruitment end date

2022-05-20, 1401/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of the effectiveness of adjunctive application of transcranial direct current stimulation (tDCS) in the management of patients with super-refractory convulsive status epilepticus

Public title

The evaluation of the effectiveness of transcranial direct current stimulation (tDCS) in the management of super-refractory convulsive status epilepticus

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Male or female (non-pregnant female) patients between the ages of 18 and 70 years Patients with a diagnosis of super-refractory convulsive status epilepticus

Exclusion criteria:

Patients with major psychiatric diseases Drug addiction Seizures are caused by metabolic abnormalities. pregnancy cranial defects The existence of additional electrical devices used to treat a variety of disorders Psychologic nonepileptic seizures

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Not randomized

Randomization description**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

Medical Sciences Review Board and Ethics Committee (IRCT)

Street address

Namazi Sq., Zand St.

City

Shiraz

Province

Fars

Postal code

7193613311

Approval date

2022-02-07, 1400/11/18

Ethics committee reference number

IR.SUMS.MED.REC.1400.561

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

Super-refractory convulsive status epilepticus

ICD-10 code

G40.911

ICD-10 code description

Epilepsy, unspecified, intractable, with status epilepticus

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

Evaluation of the effectiveness of adjunctive use of intracranial direct current stimulation in reducing convulsive movements in patients with super-refractory status epilepticus

Timepoint

Evaluation of convulsive movements of patients before the intervention and 30 minutes after the intervention

Method of measurement

According to a neurology resident's direct observation and examination of the patients,

2**Description**

Evaluation of the effectiveness of adjunctive use of intracranial direct current stimulation in improving EEG in patients with super-refractory status epilepticus

Timepoint

Patients' levels of awareness were measured before and 30 minutes after the intervention.

Method of measurement

According to the Glasgow Coma Scale

3**Description**

Evaluation of the effectiveness of adjunctive use of intracranial direct current stimulation in improving EEG in patients with super-refractory status epilepticus

Timepoint

Before and 30 minutes after the intervention, get an

electroencephalogram.

Method of measurement

electroencephalogram interpretation by a qualified and specialized epileptologist.

Secondary outcomes

empty

Intervention groups

1

Description

control group: Control group: Patients with super-refractory convulsive status epilepticus who will receive all standard treatments for status epilepsy as follows: Normally, benzodiazepines (diazepam or lorazepam, CHEMIDAROU.Co) are used in the first line of treatment. If the seizure does not stop, in the next step, intravenous anticonvulsants such as phenytoin (Caspian Tamin Co), levetiracetam (COBEL DAROU Co), or intravenous valproate (RAHA Co) are used, and if there is still evidence that the seizure persists after two hours despite treatment steps 1 and 2, the patient will be placed under general anesthesia.

Category

Treatment - Other

2

Description

Intervention group: Patients with super-refractory convulsive status epilepticus who will continue their seizures after receiving the standard treatment for seizures will be electrically stimulated through the skull with tDCS. In this way, after installing the relevant leads in the T5 and F4 areas, they will receive an electrical excitation of 2 mA for 20 minutes and the same amount of electrical excitation on the opposite side in the T6 and F3 areas for 20 minutes. Additionally, they will have an electroencephalogram 30 minutes prior to and 30 minutes following electrical stimulation.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi hospital

Full name of responsible person

Marzie Salimi

Street address

Epilepsy department, Namazi hospital, Namazi Sq, Zand St

City

Shiraz

Province

Fars

Postal code

7193613311

Phone

+98 71 3612 5840

Email

Salimi.md67@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mahtab Memarpour

Street address

Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd

City

Shiraz

Province

Fars

Postal code

71345-1978

Phone

+98 71 3235 7282

Fax

+98 71 3230 7594

Email

vcrcdep@sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Marzie Salimi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Neurology

Street address

Epilepsy Department, Namazi Hospital, Namazi Sq,
Zand St.

City

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Resident

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Person responsible for updating data

Contact

Name of organization / entity

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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 collected deidentified IPD is to be shared.

When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

People working in academic institutions

Under which criteria data/document could be used

To help further research to improve the treatment of refractory temporal lobe epilepsy

From where data/document is obtainable

Marzie salimi- Salimi.md67@gmail.com

What processes are involved for a request to access data/document

Send their request to the mentioned email address and within one working week, if there is no problem, the data will be sent to them.

Comments