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 lable 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)

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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

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Shiraz

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7193613311

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Mahtab Memarpoor

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

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Email
vcrdep@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
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Person responsible for scientific inquiries

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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 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