

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Evaluating the effectiveness of transcranial direct current stimulation (tDCS) in the management of patients with super-refractory status epilepticus: A randomized clinical trial study

Protocol summary

Study aim

Determining the effectiveness of transcranial direct current stimulation (tDCS) in the management of patients with super-refractory status epilepticus

Design

A phase 3 RCT with 20 patients with super-refractory status epilepticus in each case and control group in parallel without blinding

Settings and conduct

This study is conducted in the CPR of Shiraz Namazi Hospital on patients with epilepsy resistant to drug treatment. After consulting the neurology service, the patients will be visited by the resident, history and physical examination, and routine laboratory tests including CBC, BUN, Cr, Ca, Mg, ph are taken, and if they meet the inclusion criteria they will be randomly placed in one of the groups. Also, EEG will be taken before and after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-aged 18 to 70 years old 2-Diagnosis of super-refractory status epilepticus Exclusion criteria: 1-Psychological seizures and Suffering from major psychological diseases 2-sepsis and multi-organ failure 3-pregnancy

Intervention groups

The intervention group includes patients with drug-resistant super-refractory status epilepticus resistance to drug treatment admitted to this center. Also, they should not have the following conditions: drug addiction, metabolic diseases that cause seizures, pregnancy, skull defects, and the presence of other electrical devices to treat various diseases. This group receives the intervention in the form of two electrical stimulations for 20 minutes on each side. The comparison group includes patients with drug-resistant super-refractory status epilepticus who compared to the intervention in the form of installing LEDs in the right place without receiving

stimulation, only with EEG.

Main outcome variables

changes of convulsive movements; number of epileptiform waves in EEG

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230209057371N1**

Registration date: **2023-10-21, 1402/07/29**

Registration timing: **registered_while_recruiting**

Last update: **2023-10-21, 1402/07/29**

Update count: **0**

Registration date

2023-10-21, 1402/07/29

Registrant information

Name

Maryam Rohani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4968

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-02, 1402/07/10

Expected recruitment end date

2024-10-01, 1403/07/10

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the effectiveness of transcranial direct current stimulation (tDCS) in the management of patients with super-refractory status epilepticus: A randomized clinical trial study

Public title
Evaluation of the effect of intracranial direct current in patients with seizures

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 patients aged 18 to 70 years patients diagnosed with super refractory status epilepticus type of tonic-clonic seizure admitted to the cardiopulmonary resuscitation (CPR) ward or the emergency room of Namazi Hospital, Shiraz, Iran.
Exclusion criteria:
 Psychological seizures or Suffering from major psychological diseases Drug addiction Metabolic diseases causing seizures Pregnancy Skull abnormalities The existence of other electrical devices for the treatment of various diseases

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

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be done by using the block method of 20 pieces of paper written: TCDS and on the other 20 pieces "No intervention" will be written. Then all the crumpled papers will be poured into a container and mixed. Then, they will be taken out one by one and entered into the list from number 1 to 40. After that, forty sealed envelopes, which will be numbered up to 40 on the back, and the corresponding intervention method written inside each one, will be kept in the department's closet, and when each patient enters the study, the corresponding envelope will open in order and According to the written text, appropriate action will be taken.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Zand str., Shiraz medical school

City

Shiraz

Province

Fars

Postal code

7134846114

Approval date

2023-04-16, 1402/01/27

Ethics committee reference number

IR.SUMS.MED.REC.1402.043

Health conditions studied

1

Description of health condition studied

super-refractory status epilepticus

ICD-10 code

G40.803

ICD-10 code description

Other epilepsy, intractable, with status epilepticus

Primary outcomes

1

Description

Evaluate the change in the convulsive movements

Timepoint

From the beginning of the seizure and its end till 24 hours

Method of measurement

By physical examination and direct observation of the presence or absence of any tonic, clonic, and myoclonic convulsive movements of the patient by the neurology assistant.

2

Description

Epileptiform waves in the electroencephalography (EEG)

Timepoint

30 minutes before and after the intervention

Method of measurement

Electroencephalograph

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients whose seizures did not stop 24 hours after general anesthesia despite receiving standard seizure treatment drugs (intervention number 2) receive twice intracranial direct current stimulation by operating the relevant leads for 20 minutes at the rate of 2 milliamps, electrical stimulation will be done once in F4 and T5 areas and once again in the opposite side header in F3 and T6 areas.

Category

Treatment - Other

2

Description

All patients in each group will receive standard seizure treatments as usual (usually benzodiazepine drugs are used in the first stage of treatment.) If the seizures do not stop, intravenous anticonvulsants such as fennel are used in the next stage. Tween, levotirastam or valproate are used. If after two hours there is still evidence of continued seizures despite the steps 1 and 2, the patient will be put under general anesthesia and there will be no interruption in their usual treatment process.

Category

Treatment - Drugs

3

Description

Intervention group: History, physical examination, and blood sample for ca, Mg, phosphorus, BUN, Cr for the diagnosis and evaluation

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi hospital

Full name of responsible person

Maryam Rohani

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Namazi hospital, Zand street, Shiraz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Abbas Rezaeian Zadeh

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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

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

Maryam Rohani

Position

Neurology 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)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

"there is no further information"

Study Protocol

No - There is not 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

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

Data Dictionary

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