

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### The Efficacy of High Definition anodal transcranial direct current stimulation in shortening of duration of hospitalization in Epilepsy Monitoring Unit of patients with drug-resistant epilepsy

#### Protocol summary

##### Study aim

Determining the efficacy of brain stimulation in shortening hospitalization in epilepsy monitoring unit patients with refractory epilepsy

##### Design

Randomised, parallel group (two group) trial with blinded outcome assessment.

##### Settings and conduct

The present study conducted in the Dr. Bahonar hospital, Kerman and in each group 20 patients were assessed. patients, main investigator and data analyser did not know the patients allocations.

##### Participants/Inclusion and exclusion criteria

The conditions for entering the study are: 1) patients with drug resistant epilepsy with the criteria of the International League against Epilepsy (ILAE) 2) Age over 18 years 3) Obtaining the signed consent of all patients. The exclusion criteria are: (1) scalp diseases (eg eczema, skin lesions); (2) previous intracranial surgery, metal inside the head (outside the mouth) such as debris, surgical clips; Heart pacemaker, VNS, cochlear implant; (4) recurrent or severe headaches; (5) previous head injury and other brain-related diseases; and (6) pregnancy and breastfeeding.

##### Intervention groups

Group one : Ten participants (experimental group) receive anodic stimulation in a 2 mA current for 30 minutes for 10 consecutive days on the epileptogenic area, which is localized by long-term video-ECG monitoring. Group two : In ten patients for sham stimulation, the electrodes are placed in exactly the same position as the active stimulation on the scalp and the patient receives stimulation for only 60 seconds. However, the electrodes remain in place for 30 minutes. . The flow increases slowly in the first 15 seconds and decreases slowly in the last 15 seconds. Patients develop a sense of pruritus and murmur, but receive no flow for

the remaining 29 minutes.

##### Main outcome variables

Change in hospital admission duration in epilepsy monitoring unit

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200111046082N2**

Registration date: **2020-04-10, 1399/01/22**

Registration timing: **prospective**

Last update: **2020-04-10, 1399/01/22**

Update count: **0**

##### Registration date

2020-04-10, 1399/01/22

##### Registrant information

##### Name

Soheila Rezakhani jafarabadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3226 4196

##### Email address

drrezakhani@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-06-20, 1399/03/31

##### Expected recruitment end date

2021-06-21, 1400/03/31

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
The Efficacy of High Definition anodal transcranial direct current stimulation in shortening of duration of hospitalization in Epilepsy Monitoring Unit of patients with drug-resistant epilepsy

**Public title**  
Determining the Efficacy of Brain Electrical Stimulation in Shortening the Hospitalization of Patients With drug resistant epilepsy

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Patients with drug-resistant epilepsy as defined by the International League against epilepsy (ILAE) Over 18 years old In all patients, the probable epileptogenic zone is localized according to the epilepsy semiology and consecutive previous EEGs, and epileptogenic lesions are diagnosed by brain MRI with epilepsy protocol.  
**Exclusion criteria:**  
Under 18 years old generalized epilepsy scalp diseases such as eczema , cutaneous lesions , previous intracranial surgery previous intracranial surgery, intracranial metal (out of mouth) such as tracking, surgical clip implanted device such as cardiac pace maker, VNS, cochlear implant severe and recurrent headaches

**Age**  
From **18 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant
- Investigator
- Data analyser

**Sample size**  
Target sample size: **40**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
In this study, patients were randomly divided into two groups of 20 each. Randomization was performed using random sequencing with the help of SAS statistical software. Patients were divided into treatment and control groups according to the order of entry based on this sequence. Sealed envelopes were used to hide random allocation.

**Blinding (investigator's opinion)**  
Triple blinded

**Blinding description**  
Patients, main investigator and data analyser were masked of patients allocation. patients did not know the

name of group and treatments. we used Sham for patients in control group. all questionnaire completed in different periods without name and only the related nurse know the patients allocations.

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Ethics committee of Kerman university of Medical Sciences

###### **Street address**

Vice-challenger of Research, Ebn-e sina St., Jahad blvd.

###### **City**

Kerman

###### **Province**

Kerman

###### **Postal code**

7619813159

##### **Approval date**

2020-01-27, 1398/11/07

##### **Ethics committee reference number**

IR.KMU.REC.1398.194

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

drug resistant epilepsy

##### **ICD-10 code**

G40.21

##### **ICD-10 code description**

Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable

### **Primary outcomes**

#### **1**

##### **Description**

Investigating changes in hospitalization duration in epilepsy monitoring unit

##### **Timepoint**

The frequency of epileptic seizures will be recorded in both groups for 7 days.

##### **Method of measurement**

Record the number of attacks

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Twenty patients diagnosed with drug-resistant epilepsy will be studied according to the definition of the International league against Epilepsy (ILAE) after approval by the Ethics and Signature of consent. In all patients with possible epileptogenic zone according to semiology. The patient's previous epilepsy and lumbar strips are localized, and epileptogenic lesions are diagnosed by MRI of the brain with epilepsy protocols. Their antiepileptic drugs are discontinued during hospitalization in the EMU. Participants are randomly assigned to the experimental or sham group. Ten participants (experimental group) performed HD a-tDCS intervention in a current of 2 mA to fashion. They receive 30 minutes on the second day of hospitalization in the EMU twice in 4 hours on the epileptogenic zone.

#### Category

Treatment - Devices

### 2

#### Description

Control group: Twenty patients diagnosed with drug-resistant epilepsy will be studied according to the definition of the International league against Epilepsy (ILAE) after approval by the Ethics and Signature of consent. In all patients with possible epileptogenic zone according to semiology. The patient's previous epilepsy and lumbar strips are localized, and epileptogenic lesions are diagnosed by MRI of the brain with epilepsy protocols. Their antiepileptic drugs are discontinued during the hospitalization period in the EMU. Ten people (sham group) receive sham tDCS using the same position of the electrode.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Clinic Besat

##### Full name of responsible person

Soheila Rezakhani

##### Street address

Besat clinic, Doctor Bahonar hospital, 6th Gharanee Street

##### City

Kerman

##### Province

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7613747181

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+98 34 3223 5011

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kerman University of Medical Sciences

##### Full name of responsible person

Abbas Pardakhty

##### Street address

Vice-challenger of Research, Ebn-e sina St., Jahad blvd.

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abpardakhty@kmu.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Kerman 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

Kerman University of Medical Sciences

##### Full name of responsible person

Soheila Rezakhani Jafarabadi

##### Position

Assistant professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Neurology

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## Person responsible for scientific inquiries

**Contact**

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**Full name of responsible person**

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**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

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Soheila Rezakhani Jafarabadi

**Position**

Assistant professor

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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**

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