Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

The Efficacy assessment of high definition cathodal transcranial direct current stimulation in treatment of patients with drug-resistant epilepsy

Protocol summary

Study aim
Determining the efficacy of brain stimulation in improving patients with drug-resistant 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
patients with drug resistant epilepsy over 18 years of age that were not good candidate for epilepsy surgery or waiting for this type of surgery

Intervention groups
Group one : Ten participants (experimental group) receive cathodic stimulation in a 2 mA current for 30 minutes for 10 consecutive days on the epipeptogenic 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
Reduction of epileptic seizures in patients with drug resistant epilepsy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200111046082N1**
Registration date: **2020-04-03, 1399/01/15**
Registration timing: **retrospective**

Last update: **2020-04-03, 1399/01/15**
Update count: **0**

Registration date
2020-04-03, 1399/01/15

Registrant information

Name
Soheila Rezakhani jafarabadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 34 3226 4196

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-05-05, 1397/02/15

Expected recruitment end date
2019-05-31, 1398/03/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Efficacy assessment of high definition cathodal transcranial direct current stimulation in treatment of patients with drug-resistant epilepsy

Public title
The assessment efficacy of electrical brain stimulation

among patients with drug-resistant epilepsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age>=18 y/o all of patients full filled ILAE criteria of drug-resistant epilepsy participants were not good candidate for epilepsy surgery and or they will not surgery or they waited for epilepsy surgery. obtaining signed consent

Exclusion criteria:

scalp diseases(such as eczema, skin lesions) previous intracranial surgery, intracranial metal (out of mouth) such as cracking, surgical clip implanted device such as cardiac pacemaker, VNS, Cochlear implantation recurrent or severe headaches previous head trauma and other related brain diseases pregnancy and lactation

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **22**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, patients randomly divided in two groups (20 patients in each group) using random allocation sequence with SAS statistical software. according to this method a simple randomization list product and patients`involvement in each group determine base on order entry. we used sequentially numbered, sealed opaque envelopes for allocation concealment. patients (individuals) were the randomization units.

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.

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Province

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Postal code

7619813159

Approval date

2018-08-13, 1397/05/22

Ethics committee reference number

IR.KMU.REC.1397.191

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 the frequency of epileptic seizures

Timepoint

before intervention and monthly for 3 months

Method of measurement

seizure diary

2

Description

Investigating the frequency changes of interictal epileptiform discharges

Timepoint

immediately before and after intervention and then monthly for 3 months

Method of measurement

30 minutes standard EEG

3

Description

side effects

Timepoint
immediately after stimulation
Method of measurement
specialist visit

4

Description
quality of life
Timepoint
before intervention and after 3 months
Method of measurement
full filling of the QoL in Epilepsy Inventory-89

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Patients with drug-resistant epilepsy who are not good candidates for epilepsy surgery or who do not want surgery or are waiting for surgery. In all patients, the epileptogenic zone is localized during prolonged EEG video-EEG monitoring, and epileptogenic lesions are diagnosed by brain epilepsy with epilepsy protocol. Their antiepileptic drugs did not change during the study period. Participants are randomly assigned to an experimental or sham group. Ten participants (experimental group) received HD c-tDCS intervention in a 2 mA current for 30 minutes for 10 consecutive days over the epileptogenic zone. The standard 30-min brain tape will be administered in two groups immediately before and after the first and monthly stimulation for three months. Patients will also be tracked by the cigarette calendar. The frequencies of the intraectal epiglottis signals and waves before and after HD C-TDCS will be compared statistically. Quality of life (QoL) of patients will be assessed by QoL-Epilepsy Questionnaire -89 before the intervention and after three months. After each session of stimulation, side effects will be questioned and recorded.
Category
Treatment - Devices

2

Description
Control group: Patients with drug-resistant epilepsy who are not good candidates for epilepsy surgery or who do not want surgery or are waiting for surgery. In all patients, the epileptogenic zone is localized during prolonged EEG video-EEG monitoring, and epileptogenic lesions are diagnosed by brain epilepsy with epilepsy protocol. Their antiepileptic drugs did not change during the study period. Participants were randomly assigned to the experimental or sham group. In ten patients for sham stimulation, the electrodes were placed in exactly the same position as the active stimulation on the scalp and the patient received stimulation for only 60 seconds. The remaining 30 minutes remain in place. 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.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinic Besat
Full name of responsible person
Soheila Rezakhani Jafar abadi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
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

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Neurology

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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

Not applicable

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