Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effects of trans cranial direct current stimulation on brain through skull on somatic and psychiatric symptom of elderly women with fibromyalgia

Protocol summary

Summary

Objectives: The current study would be carried out to determine the effects of trans-cranial direct current stimulation on brain through skull on somatic and psychiatric symptoms of elderly women with fibromyalgia. Participants: Among the attendants of rheumatology clinic of Rasool Akram hospital, Tehran, Iran; 50 elderly female volunteers with fibromyalgia would be selected. Design and Setting: The participants will be randomly divided into 2 groups, 25 of active stimulation and 25 of sham stimulation by the secretary of the clinic. The patients would be recognized by a code. The patients would receive the primary evaluation and tDCS intervention or placebo-therapy. Not the divider nor the patient and the analyzer would be aware of belonging of the patient to these two groups. Only the operator is aware of this, and after the finishing of the study, he will reveal the codes. The patients would be divided into A and B groups randomly, a group would receive active stimulation and the other would receive sham stimulation. Both groups would be compared. Interventions: The stimulation's characteristics are 2 mA, for 20 minutes, anode on M1 and cathode on right supra-orbital in active group and simulated condition in sham group are 2mA for 30 seconds. Main outcome: All will pass BECK, HAM, FIQ, VAS, SF36 test, before, after 10 session of tDCS or sham stimulation and after 1 month. The outcomes of both active and sham groups will be compared. The analysis and interview would be performed by blinded operators.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201606091959N8**

Registration date: **2017-01-15, 1395/10/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-01-15, 1395/10/26

Registrant information

Name

Seyed Kazem Malakouti

Name of organization / entity

Iran University of Medical Science - Tehran Psychiatric Institute

Country

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Science

Expected recruitment start date

2016-11-20, 1395/08/30

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of trans cranial direct current stimulation on brain through skull on somatic and psychiatric symptom

of elderly women with fibromyalgia

Public title
The effects of trans cranial direct current stimulation on brain through skull on somatic and psychiatric symptom of elderly women with fibromyalgia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: patients with fibromyalgia according to ACR-90; older than 50 years and female; Medications the patient has not changed during the 8 weeks ago and medically was stable. Exclusion criteria: psychiatric disease or chronic pain disorder in medical evaluation; history of substance abuse; history of Neurological diseases; cardiac pace maker; history of deep brain stimulation surgery.
Age
No age limit
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical committee of Iran University of Medical Sciences
Street address
Hemmat Highway
City
Tehran
Postal code
1449614535
Approval date
2015-11-22, 1394/09/01
Ethics committee reference number
IR.IUMS.REC.1394.9211497002

Health conditions studied

1

Description of health condition studied
fibromyalgia
ICD-10 code
M79.7
ICD-10 code description
fibromyalgia

Primary outcomes

1

Description
pain
Timepoint
before, after and 1 months after interventions
Method of measurement
Visual Analogue Scale questionnaire

Secondary outcomes

1

Description
function
Timepoint
before, after and 1 months after interventions
Method of measurement
FIQ Questionnair

2

Description
depression
Timepoint
before, after and 1 months after interventions
Method of measurement
BDI Questionnair

3

Description
quality of life
Timepoint
before, after and 1 months after interventions
Method of measurement
SF36 Questionnair

4

Description
anexity
Timepoint
before, after and 1 months after interventions
Method of measurement
HAM Questionnair

Intervention groups

1

Description
In the active group, 20 minutes, 2mA direct current stimulation, Anode at primary motor cortex and cathode at right supra-orbital is given.
Category
Treatment - Other

2

Description
In the control group, 30 seconds, 2mA stimulation with 5 seconds RAMP-UP and RAMP-Down current is given to make the patient have a similar emotion to active group at the skull
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Rhomatologic Clinic of Rasoole Akram hospital
Full name of responsible person
Zhale Zandie
Street address
Rasoole Akram hospital, Sattar Khan, Tehran
City
Tahran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
vice chancellor for research, Iran University of Medical Sciences
Full name of responsible person
Dr. Seyed Kazem Malakouti
Street address
Iran University of Medical Science, shahid Hemmat highway, Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
vice chancellor for research, Iran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Iran University of Medical Science
Full name of responsible person
Dr Zhale Zandie
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resident of geriatric medicine
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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)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty