Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effectiveness of RTMS and TDCS in decreasing pain and improving quality of life in fibromyalgia patients

Protocol summary

Study aim

Comparing effect of transcranial direct current stimulation (TDCS) and repetitive transcranial magnetic stimulation (RTMS) on pain reduction and improvement the quality of life in patients with Fibromyalgia

Design

This is double blinded clinical trial,with parallel groups ,with 30 patients suffering fibromyalgia , referring to the physical medicine and rehabilitation clinics of IRAN university of medical sciences in 1396-97 .The patients are divided into 2 parallel groups by block randomization using sealed envelopes, and follow up are considered for 6 and 12 weeks later.The inclusion criteria are age over18 years and vas>4 .Follow up is performed after 3 session of treatment ,6 and12 weeks later.

Settings and conduct

Our study is performed on the patients with Fibromyalgia, referring to physical medicine and rehabilitation clinics of Iran university medical sciences during 1396-97.Blinding is applied on the patients and analyzer(they do not know about 2 different methods of stimulation).The patients are divided into 2 groups by block randomization using sealed envelopes.

Participants/Inclusion and exclusion criteria

Patient over 18 y/o with fibromyalgia with an Visual analog scale (VAS>4),who have no severe diseases that may interfere with the study and do not have a metal implant

Intervention groups

Patients are randomly divided into 2groups: group A: 3 sessions of TDCS . The anode is placed on the left Dorsolateral prefrontal cortex (DLPFC) ,and the cathode is placed on the right supraorbital region.stimulation is performed with intensity 2 mA and dose 40 for 20 minutes. group B: 3 sessions of RTMS. stimulation is given on the left DLPFC with high frequency (10 Htz) ,intensity 100% of the threshold, rest time of 15 second and a total pulse of 1000 .Also patient perform specific exercises.

Main outcome variables

1.pain 2.quality of life 3. anxiety and depression 4.health condition

General information

Reason for update

Acronym

TDCS

IRCT registration information

IRCT registration number: **IRCT20180220038802N1**
Registration date: **2018-12-02, 1397/09/11**
Registration timing: **retrospective**

Last update: **2018-12-02, 1397/09/11**
Update count: **0**

Registration date

2018-12-02, 1397/09/11

Registrant information

Name

Hosnieh Haqiqat shenas

Name of organization / entity

Country

Iran (Islamic Republic of)

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hosnie64.haq23@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-25, 1396/11/05

Expected recruitment end date

2018-06-22, 1397/04/01

Actual recruitment start date

2018-01-25, 1396/11/05

Actual recruitment end date
2018-06-30, 1397/04/09
Trial completion date
2018-09-22, 1397/06/31

Scientific title
Comparison of the effectiveness of RTMS and TDCS in decreasing pain and improving quality of life in fibromyalgia patients

Public title
Effect of TDCS in treatment of fibromyalgia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
American college of rheumatology 's criteria for fibromyalgia Age >18 VAS >=4 (1week before study)
Exclusion criteria:
The patient desire to leave the study at each stage of the plan major depression (beck score>30) or psychosis Diseases that disrupts the process ,such as diagnosed DM ,heart ,liver , pulmonary or kidney diseases Pregnancy and lactation Metal implant History of seizure or epilepsy
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **30**
Actual sample size reached: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization using sealed envelopes into 2 groups
Blinding (investigator's opinion)
Double blinded
Blinding description
Patient and person who analyze data, do not know about the distribution of patients to the tow treatment groups with electrical and magnetic stimulation.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, Hemmat Highway, Tehran
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2018-01-21, 1396/11/01
Ethics committee reference number
IR.IUMS.FMD.REC 1396.9511524003

Health conditions studied

1

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

Primary outcomes

1

Description
The severity of pain
Timepoint
Zero, The last day of treatment, 6 and 12 weeks later
Method of measurement
Visual analog scale (vas)

2

Description
The quality of life
Timepoint
Zero ,6 and 12 weeks later
Method of measurement
By SF36 questionnare

3

Description
The depression and anxiety
Timepoint
Zero, 6 and 12 weeks later
Method of measurement
DASS questionnare

4

Description

Health condition in fibromyalgia

Timepoint

Zero, 6 and 12 weeks later

Method of measurement

FIQ questionnare

Secondary outcomes

1

Description

Side effects

Timepoint

6 and 12 weeks later

Method of measurement

Physical exam

Intervention groups

1

Description

Intervention group: Brain electrical stimulation using TDCS (Transcranial direct current stimulation)in left DLPFC (Dorsolateral prefrontal cortex) , which will be done by an experienced physical medicine and rehabilitation specialist.

Category

Treatment - Other

2

Description

Control group: Brain magnetic stimulation by RTMS(Repetitive transcranial magnetic stimulation) in left DLPFC ,which will be done by an experienced physical medicine and rehabilitation specialist

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Firuzgar Hospital

Full name of responsible person

Dr .Hosnie Haghighatshenas

Street address

Department of Physical Medicine and Rehabilitation , Firuzgar Hospital , Valiasr Square ,Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Dr.Hosnie Haghighatshenas

Position

Resident of Physical Medicine and Rehabilitation

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Associated Professor of Physical Medicine and Rehabilitation

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

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
After unidentified participants ,data can be shared.

When the data will become available and for how long
After the results are published.

To whom data/document is available
People working in academic institute

Under which criteria data/document could be used
If other researchers want to perform additional analysis on the data, other than published, their request will be discussed in an authors meeting

From where data/document is obtainable
Via investigator's email (dr.sajadi_pmr@yahoo.com)

What processes are involved for a request to access data/document
The applicant should email his/her request and the reason for doing it.

Comments