# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 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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**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**

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**Full name of responsible person**

Dr. Javad Ali Musavi

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Dr.Sajadi_PMR@Yahoo.com

**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

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## Person responsible for updating data

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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**