

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Comparison of therapeutic effects of M1 and Bifrontal transcranial direct current stimulation montages in treatment of shoulder girdle myofascial syndrome: A randomized clinical trial.

Protocol summary

Study aim

Comparison of therapeutic effects of M1 and Bifrontal transcranial direct current stimulation montages in treatment of shoulder girdle myofascial syndrome

Design

A randomized, blinded, sham controlled clinical trial with a parallel group design of 60 patients

Settings and conduct

The studied patients will be selected from all the patients referred to the physical medicine and rehabilitation clinics of Tabriz University of Medical Sciences, in which the inclusion and exclusion criteria applied and they will be willing to participate in the study. Patients will be studied in two groups with different assemblies and the third group as Sham therapy. For blinding patients and analyzer, information about the type of assembly or sham treatment, will not be provided.

Participants/Inclusion and exclusion criteria

1. Diagnosis of chronic myofascial pain in the shoulder girdle. 2. A history of at least 3 months of pain due to shoulder girdle myofascial pain syndrome. 3. Spontaneous pain in at least one of the trigger points in the trapezius, supraspinatus, rhomboid, and levator scapulae muscles. 4. Use of stable dose of painkillers, at least 3 months prior to the study. 5. Pain intensity of 5 or greater with VAS criteria over the past week. 6. Age between 18 and 50 years old.

Intervention groups

Patients will be studied in three groups, A, B and C. Group A will be treated with the first type of montage, group B will be treated with second type montage and group C will be treatment as sham therapy.

Main outcome variables

1. Investigating the therapeutic effects of Bifrontal TDCS and M1 TDCS montages on pain relief, pain pressure threshold and pain self perception in patients with shoulder girdle myofascial pain syndrome and to

comparison the therapeutic effects of these two montages.

General information

Reason for update

Acronym

TDCS

IRCT registration information

IRCT registration number: **IRCT20081004001292N6**

Registration date: **2020-06-06, 1399/03/17**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-06, 1399/03/17**

Update count: **0**

Registration date

2020-06-06, 1399/03/17

Registrant information

Name

Vahideh Toopchizadeh

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 984113335625

Email address

toopchi@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2021-05-22, 1400/03/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of therapeutic effects of M1 and Bifrontal transcranial direct current stimulation montages in treatment of shoulder girdle myofascial syndrome: A randomized clinical trial.

Public title
Comparison of the therapeutic effects of M1 and Bifrontal TDCS in the treatment of patients with shoulder girdle myofascial syndrome.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Diagnosis of chronic myofascial pain in the shoulder girdle. A history of at least 3 months of pain due to shoulder girdle myofascial pain syndrome. Spontaneous pain in at least one of the trigger points in the trapezius, supraspinatus, rhomboid, and levator scapulae muscles. Use of stable dose of painkillers, at least 3 months prior to the study. Pain intensity of 5 or greater with VAS criteria over the past week. Age between 18 and 50 years old.
Exclusion criteria:
 Previous diagnosis of shoulder pathology other than MPS that can help with pain, including partial dislocation, instability, fracture, frozen shoulder, infection and inflammation. Cervical radiculopathy based on clinical examinations. Diagnosis of neurological diseases such as Alzheimer's or Parkinson's. Severe psychological conditions or symptoms such as schizophrenia, major depression or mania. Current pregnancy or lactation. History of seizures. Defects in the skull bone. Existence of skin scar at the electrode installation site. Tumors in the tissue of the areas below the electrode. Current use of herbal remedies or other alternative therapies such as recent topical injections for pain.

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
To randomize patients, 60 envelopes will be prepared and numbered from one to 60. Using a table of random numbers, patients will be divided into three groups, A, B, and C. According to the table obtained, the group for

each number will be written in the envelope. A list of the number of patients will be prepared and as patients enter the study, patient envelope number will be open and the patient will be placed in the specified group.

Blinding (investigator's opinion)

Double blinded

Blinding description

To blind the patients, they will not receive information about whether the treatment is Sham or the difference in the type of montages. In blinding analyzer, the type of montages or the type of therapy (Sham or true) received by patients will not be provided to the analyzer.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Faculty of Medicine, Next to Imam Reza Hospital/Golgasht Avenue/ Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2020-05-30, 1399/03/10

Ethics committee reference number

IR.TBZMED.REC.1399.168

Health conditions studied

1

Description of health condition studied

Myofascial pain syndrome

ICD-10 code

M79.1

ICD-10 code description

Myalgia

2

Description of health condition studied

Myofascial pain syndrome

ICD-10 code

G89.4

ICD-10 code description

Chronic pain syndrome

Primary outcomes

1

Description

Pain threshold

Timepoint

Before and immediately after the intervention

Method of measurement

Wagner digital Pain algometer

2

Description

Self-Perception of improvement

Timepoint

Before and immediately after the intervention

Method of measurement

Pain Self-Efficacy Questionnaire (PSEQ)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention First group: transcranial direct current stimulation M1 montage

Category

Treatment - Devices

2

Description

Intervention Second group: transcranial direct current stimulation Bifrontal montage

Category

Treatment - Devices

3

Description

Control group: Sham therapy

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Physical Medicine and Rehabilitation clinic of Emam Reza hospital

Full name of responsible person

Fariba Eslamian

Street address

Emam Reza hospital, Golgasht avenue, Azadi street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 41 3334 5081

Fax

+98 41 3335 2073

Email

imamreza@tbzmed.ac.ir

Web page address

<https://imamreza.tbzmed.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Samiee

Street address

Faculty of Medicine, Next to Imam Reza Hospital/Golgasht Avenue/ Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3335 7311

Fax

+98 41 3334 4280

Email

research-vice@tbzmed.ac.ir

Web page address

<https://researchvice.tbzmed.ac.ir>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Behzad Izadseresht

Position

Resident of Physical Medicine and Rehabilitation

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

Street address

Imam Reza Hospital/Golgasht Avenue/ Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3326 8029

Email

b.izadseresht@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Vahideh Toopchizadeh

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

Street address

Faculty of Medicine, Next to Imam Reza Hospital/Golgasht Avenue/ Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3334 5081

Email

toopchi@tbzmed.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Behzad Izadseresht

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

Street address

Imam Reza Hospital/Golgasht Avenue/ Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3326 8029

Email

b.izadseresht@yahoo.com

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

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

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

Title and more details about the data/document

All potential data will be shared after contestants are anonymised

When the data will become available and for how long

I haven't decided yet

To whom data/document is available

Only for researchers working in academic institutions

Under which criteria data/document could be used

There are no other conditions.

From where data/document is obtainable

Email the person in charge of updating.

What processes are involved for a request to access data/document

The release schedule is unknown

Comments