

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Comparison of the effects of pharmacotherapy and action potential simulation therapy in patients with extracapsular temporomandibular disorders

Protocol summary

Study aim

Evaluation of action potential simulation therapy on patients with temporomandibular disorders

Design

Randomized Clinical Trial with control group, parallel groups, none blind, 38 patients. Randomization with block randomization of blocks of 4

Settings and conduct

Department of oral surgery, faculty of dentistry, Tehran Islamic Azad Medicine Sciences

Participants/Inclusion and exclusion criteria

All patients diagnosed with mild and moderate temporomandibular disorders according to DC-TMD criteria who do not present with history of trauma to tmj, seizure and epilepsy, having a cardiac pacemaker, current pregnancy, condylar displacement without reduction, candidacy for tmj surgery, and history of orthognatic surgery

Intervention groups

Intervention group: First, a thin layer of lubricating gel is applied at the area between the electrodes and skin. The negative electrode is placed on the origin of the pain (tmj) and the positive electrode is placed on the attachment of masseteric muscle. Each therapeutic session is consisted of a 10-minute intervention with the power of the APS machine starting at 0.2mA and gradually increasing to 0.9mA. 6 therapeutic sessions are necessary as follows: 1st and 2nd session on the first day with a resting phase of 8-9 minutes between sessions 3rd and 4th sessions on the next day with a resting phase of 8-9 minutes between sessions 5th and 6th sessions four days after the initial session with a resting phase of 8-9 minutes between sessions Control group: In the control group pharmacotherapy consisting of Naproxen 500mg twice a day for 4 weeks, cyclobenzaprine 10mg every night before sleeping for 4 weeks, and diazepam 2.5mg 4 times a day for the first

week and 5mg 4 times a day for the next three weeks

Main outcome variables

Degree of temporomandibular joint pain, presence or absence of tmj sounds, limitation is lateral movement of the jaw, maximum opening of the jaw

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171216037893N5**

Registration date: **2021-06-12, 1400/03/22**

Registration timing: **registered_while_recruiting**

Last update: **2021-06-12, 1400/03/22**

Update count: **0**

Registration date

2021-06-12, 1400/03/22

Registrant information

Name

Hamidreza Mahaseni aghdam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2240 6440

Email address

h_mahaseni@dentaliau.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-10, 1399/12/20

Expected recruitment end date

2021-08-11, 1400/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of pharmacotherapy and action potential simulation therapy in patients with extracapsular temporomandibular disorders

Public title

Evaluation of action potential simulation therapy on patients with temporomandibular disorders

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients diagnosed with mild and moderate temporomandibular disorders according to DC-TMD diagnostic criteria

Exclusion criteria:

History of trauma to temporomandibular joint History of epilepsy and seizure Having cardiac pacemakers Current pregnancy Temporomandibular disc displacement without reduction Candidacy for temporomandibular joint surgery History of orthognatic surgery

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked*No information***Sample size**

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

Block Randomization with block size of 4. All patients are aware of the interventions done in both groups.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee**

Name of ethics committee

Ethics committee of Islamic Azad University of Medical Sciences, Tehran

Street address

No. 9, 9th Neyestan st., Pasdaran st.

City

Tehran

Province

Tehran

Postal code

19585175

Approval date

2021-04-28, 1400/02/08

Ethics committee reference number

IR.IAU.DENTAL.REC.1400.006

Health conditions studied**1****Description of health condition studied**

Temporomandibular disorders

ICD-10 code

M26.6

ICD-10 code description

Temporomandibular joint disorders

Primary outcomes**1****Description**

Temporomandibular joint pain

Timepoint

prior to intervention, one week after intervention, one month after intervention

Method of measurement

VAS (Visual Analog Scale)

2**Description**

Joint sounds

Timepoint

prior to intervention, one week after intervention, one month after intervention

Method of measurement

auscultation with stethoscope

3**Description**

Degree of lateral movement of mandible

Timepoint

prior to intervention, one week after intervention, one month after intervention

Method of measurement

measurement with millimetric ruler

4**Description**

Oral maximal opening

Timepoint

prior to intervention, one week after intervention, one month after intervention

Method of measurement

measurement with millimetric ruler

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group:

Category

Treatment - Devices

2**Description**

Control group:

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Department of oral and maxillofacial surgery, faculty of dentistry, tehran islamic azad medical scie

Full name of responsible person

Ramtin Dastgir

Street address

No. 9, 9th Neyestan st., Pasdaran st

City

Tehran

Province

Tehran

Postal code

19585175

Phone

+98 21 2276 3459

Email

ramtin_dastgir@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Ramtin Dastgir

Street address

No 9., 9th Neyestan st., Pasdaran st.

City

Tehran

Province

Tehran

Postal code

19585175

Phone

+98 21 2276 3459

Email

ramtin_dastgir@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Islamic Azad University

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**

Islamic Azad University

Full name of responsible person

Hamidreza Mahaseni aghdam

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Dental faculty, 9th neyestan street, pasdaran street

City

Tehran

Province

Tehran

Postal code

19585175

Phone

+98 21 2240 6440

Fax**Email**

h_mahaseni@dentaliau.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Hamidreza Mahaseni aghdam

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Dental faculty, 9th neyestan street, pasdaran street

City

Tehran

Province

Tehran

Postal code

19585175

Phone

+98 21 2240 6440

Fax**Email**

h_mahaseni@dentaliau.ac.ir

Fax**Email**

h_mahaseni@dentaliau.ac.ir

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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 data of participants is subject to sharing after anonymization

When the data will become available and for how long

Access to data granted after publication of results

To whom data/document is available

Researchers affiliated with universities

Under which criteria data/document could be used

Data can be utilized in other articles including systematic reviews. No alteration to the data is granted

From where data/document is obtainable

Dr. Hamidreza Mahaseni Aghdam :
h_mahaseni@dentaliau.ac.ir Ramtin Dastgir :
ramtin_dastgir@yahoo.com

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

Request for data must be clear and indicating of intentions and purposes. Data will be shared one month following a request.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Hamidreza Mahaseni aghdam

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Dental faculty, 9th neyestan street, pasdaran street

City

Tehran

Province

Tehran

Postal code

19585175

Phone

+98 21 2240 6440