

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The Effect of Muscle Energy Technique on Temporomandibular Joint Motion in People with Trismus of Chewing Muscles due to Third Molar Surgery

Protocol summary

Study aim

Determining the effectiveness of Muscle Energy Technique in increasing the maximum mouth opening after third molar surgery

Design

Clinical trial with intervention group and control group, randomized, On 48 patients, randomized permuted blocks were used for randomization.

Settings and conduct

This study will be performed in the Neuromuscular Rehabilitation Research Center of Semnan University of Medical Sciences in such a way that patients are randomly placed in one of the intervention or control groups, the intervention group receives MET from the first day after surgery for seven days and the control group does not receive any intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: People with inability to open their mouth after third molar extraction with an interincisal distance of less than 40 mm, people who have had 24 hours of third molar surgery, people with pain and spasm in the masticatory muscles after third molar surgery, Age between 18 and 35 years; Exclusion criteria: Degenerative Temporomandibular Joint (TMJ) arthritis, Inflammatory TMJ arthritis, Infective TMJ arthritis, Malignant tumors of the face and jaw, History of dislocation of TMJ, History of fracture of TMJ, History of previous surgery of jaw or TMJ, Hypermobility TMJ

Intervention groups

The intervention group: receives Muscle Energy Technique (MET), the control group: does not receive any intervention. In this study, to perform the MET, the patient is asked to open his mouth for 10 seconds in front of the therapist's hand under the jaw. This process is repeated 5 times in each session and after each time the jaw is moved to a newer domain before repeating the technique. This technique is performed daily for seven

days from the first day after surgery.

Main outcome variables

The degree of displacement of the Temporomandibular Joint condyle on the X and Y axis, Maximum Mouth Opening, Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211016052783N1**
Registration date: **2022-01-27, 1400/11/07**
Registration timing: **registered_while_recruiting**

Last update: **2022-01-27, 1400/11/07**

Update count: **0**

Registration date

2022-01-27, 1400/11/07

Registrant information

Name

Fatemeh Noormohammadi Ghomi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Muscle Energy Technique on Temporomandibular Joint Motion in People with Trismus of Chewing Muscles due to Third Molar Surgery

Public title

The effect of Muscle Energy Technique on Trismus after third molar surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

People with an inability to open their mouth after third molar surgery that has less than 40 mm interincisal distance People who have had 24 hours of third molar surgery People with pain and spasm in the masticatory muscles after third molar surgery Surgery of all patients is performed by a same surgeon and a same assistant surgeon in the same conditions and under local anesthesia

Exclusion criteria:

Degenerative Temporomandibular joint arthritis Inflammatory Temporomandibular joint arthritis Infective Temporomandibular joint arthritis Malignant tumors of the face and jaw History of dislocation of Temporomandibular joint History of fracture of Temporomandibular joint History of previous surgery of jaw or Temporomandibular joint Hypermobility Temporomandibular joint

AgeFrom **18 years** old to **35 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **48****Randomization (investigator's opinion)**

Randomized

Randomization description

In this study, we use the randomized permutation block method for random assignment. The procedure will be as follows: quadruple blocks with a combination of A and B (group A intervention and group B control) will be the criteria for action. Given that in quadruple blocks, six different combinations of blocks can exist, a number is assigned to each block (from 1 to 6). The number of blocks is as follows: Block 1: AABB Block 2: BBAA Block 3: ABBA Block 4: BAAB Block 5: ABAB Block 6: BABA Using a table of random numbers, considering the numbers 1 to 6 and deleting the numbers 0, 7, 8 and 9, respectively, the blocks are selected and the way of allocating patients for each of the groups A and B is done according

to the selected blocks. Obviously, the list obtained from this method of allocation will be completely random and balanced. After preparing a randomization list for each patient, they will have a number in order of enrollment (from 1 to 48). A sealed envelope is prepared with A or B written inside the envelope based on the compiled list. The researcher, who is not aware of the main list, after registering the patient who entered the study and checking the person's number, takes the relevant envelope and opens it in the patient's bedside and realizes the type of intervention based on the contents of the envelope. In this way, the researcher is not aware of the list and only after the patient entered into the study and finding out if he/she is qualified, he/she realizes the type of intervention by opening the envelope.

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 Semnan University of Medical Sciences

Street address

Headquarters of Semnan University of Medical Sciences and Health Services, Basij Blvd

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3514799442

Approval date

2021-10-31, 1400/08/09

Ethics committee reference number

IR.SEMUMS.REC.1400.187

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

Trismus following Third Molar Surgery

ICD-10 code

R25.2

ICD-10 code description

Cramp and spasm

Primary outcomes

1

Description

The degree of displacement of the Temporomandibular Joint Condyle on the X-axis

Timepoint

On the first day after surgery before and after the intervention and then on the 7th day after surgery (end of the intervention period)

Method of measurement

By Sonography and MATLAB program

2

Description

The degree of displacement of the Temporomandibular Joint Condyle on the Y-axis

Timepoint

On the first day after surgery before and after the intervention and then on the 7th day after surgery (end of the intervention period)

Method of measurement

By Sonography and MATLAB program

Secondary outcomes

1

Description

Maximum mouth opening

Timepoint

On the first day after surgery before and after the intervention and then on the 7th day after surgery (end of the intervention period)

Method of measurement

Use caliper that is calibrated in millimeter

2

Description

Intensity of pain

Timepoint

On the first day after surgery before and after the intervention and then on the 7th day after surgery (end of the intervention period)

Method of measurement

Use Visual Analogue Scale

Intervention groups

1

Description

Intervention group: Muscle energy technique, In a seated position the subject is asked to open the mouth to its comfortable limit, the operator then placed one hand around the subject's jaw, while the other hand grasped the head for stability, the subject is then asked to attempt open the mouth for 10 seconds against the resistance applied by the operator's hand placed below

the jaw, this reciprocal inhibition procedure is repeated five times, After each time, the jaw is moved to a new barrier before repeating the technique. this technique is performed from the first day after surgery daily for seven days.

Category

Rehabilitation

2

Description

Control group: They do not receive any intervention.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Neuromuscular Rehabilitation Research Center of Semnan University of Medical Sciences

Full name of responsible person

Fatemeh Noormohamadi ghomi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Fatemeh Noormohammadi ghomi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available