

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of Meloxicam with physical therapy (TENS & infrared) on improvement of TMD symptoms in the referrals to Qom medical clinics in 2018-2019

Protocol summary

Study aim

Comparative effect of the Meloxicam and physical therapy (TENS & infrared) on improvement of TMD symptoms in the Referrals to Qom medical clinics in 2018-2019

Design

The clinical trial has two treatment groups with parallel, non-blinded and randomized groups, phase 3, 46 patients

Settings and conduct

Patients referring to Qom Medical Sciences Clinics were selected according to the inclusion and exclusion criteria. Research process were explained to them and then randomly assigned to one of two treatment groups

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with a history of TMD include women and men aged 15-60 years. Exclusion criteria: Includes history of arthritis and other systemic joint diseases and articular dislocation.

Intervention groups

There were two treatment groups in this study, in the physiotherapy group patients underwent tens & infrared therapy, and in the drug group, patients used meloxicam pills

Main outcome variables

Masticator muscles tenderness, joint sounds, mouth opening limitation, subluxation, Deviation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181113041642N1**
Registration date: **2020-03-28, 1399/01/09**
Registration timing: **retrospective**

Last update: **2020-03-28, 1399/01/09**

Update count: **0**

Registration date

2020-03-28, 1399/01/09

Registrant information

Name

Melika Sharifi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3770 0094

Email address

ml_sharifi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-21, 1397/09/30

Expected recruitment end date

2019-06-10, 1398/03/20

Actual recruitment start date

2018-12-22, 1397/10/01

Actual recruitment end date

2019-05-31, 1398/03/10

Trial completion date

2019-06-24, 1398/04/03

Scientific title

Comparison of the effect of Meloxicam with physical therapy (TENS & infrared) on improvement of TMD symptoms in the referrals to Qom medical clinics in 2018-2019

Public title

effect of meloxicam & physiotherapy in TMD

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with a history of myofascial pain of TMD Both sexes Aged 15-60 years

Exclusion criteria:

Arthritis and other systemic joint diseases Articular dislocation

Age

From **15 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **46**

Actual sample size reached: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

simple randomization, all patients referred to the clinic because of musculoskeletal pain due to temporomandibular disease, divided to two groups randomly by drawing.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

Secondary trial Id

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Qom University of Medical Sciences

Street address

Shahid Lavasani St, University of Dentistry of Qom

City

Qom

Province

Ghoush

Postal code

3713649367

Approval date

2018-11-06, 1397/08/15

Ethics committee reference number

IR.MUQ.REC.1397.124

Health conditions studied

1

Description of health condition studied

temporomandibular disorder

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

masticatory muscles tenderness

Timepoint

First and last day (30) of study

Method of measurement

questionnaire and examination

2

Description

joint sounds

Timepoint

first and last day of study

Method of measurement

questionnaire and examination

3

Description

mouth opening limitation

Timepoint

first and last day of study

Method of measurement

questionnaire and examination

4

Description

subluxation

Timepoint

first and last day of study

Method of measurement

questionnaire and examination

5

Description

deviation

Timepoint

first and last day of study

Method of measurement

questionnaire and examination

6

Description

limitation on lateral movement

Timepoint

first and last day of study

Method of measurement

questionnaire and examination

Secondary outcomes

empty

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

Intervention group1: tab meloxibe 7.5 mg , for 30 days, once a day

Category

Treatment - Drugs

2**Description**

Intervention group 2: physiotherapy (tens & infrared), 10 session, 3 times in week for 4 week, 20 minutes infrared and 5 minutes tens each session

Category

Treatment - Other

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

Qom medical science hospital

Full name of responsible person

Melika Sharifi

Street address

Qom, Lavasani St, university of dentistry of Qom

City

Qom

Province

Ghoum

Postal code

9367371364

Phone

+98 25 3770 0094

Email

ml_sharifi@yahoo.com

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

Ghoum University of Medical Sciences

Full name of responsible person

Mohammad Mehdizadeh

Street address

Qom. Lavasani St .Dentistry University

City

Qom

Province

Ghoum

Postal code

3713649369

Phone

+98 25 3770 0094

Email

Mehdizadehmo19@gmail .com

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

Yes

Title of funding source

Ghoum University of Medical Sciences

Proportion provided by this source

10

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**

Ghoum University of Medical Sciences

Full name of responsible person

Mohammad Mehdizadh

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Qom, Lavasani St, University of Dentistry of Qom

City

Qom

Province

Ghoum

Postal code

3713649367

Phone

+98 25 3770 0094

Email

Mehdizadehmo19@gmail.com

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

Ghoum University of Medical Sciences

Full name of responsible person

Mohammad Mehdizadeh

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Qom, Lavasani St ,University of Dentistry of Qom

City

Qom

Province

Ghoum

Postal code

3713649367

Phone

+98 25 3770 0094

Email

Mehdizadehmo19@gmail.com

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

Ghoum University of Medical Sciences

Full name of responsible person

Mohammad Mehdizadeh

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Qom, Lavasani St , University of Dentistry of Qom

City

Qom

Province

Ghoum

Postal code

3713649367

Phone

+98 25 3770 0094

Email

mehdizadehmo19@gmail.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

Undecided - It is not yet known if there will be 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