

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

The effect of self-care in improving the symptoms of Temporomandibular Disorders in drug-treated Rheumatoid Arthritis patients

Protocol summary

Study aim

Determining the effect of self-care treatment in improving the symptoms of Temporomandibular Disorders in Rheumatoid Arthritis patients treated with drugs.

Design

Phase 2 clinical trial

Settings and conduct

The symptoms of Temporomandibular Disorders of a patient with Rheumatoid Arthritis referring to a Rheumatologist's office will be examined by a trained examiner in the first visit. Pain intensity will be evaluated using a Numerical Analog Scale. Then the necessary "self-care" training will be given. 2 months later, the patient will be examined again, similar to the first session, and the symptoms will be recorded.

Participants/Inclusion and exclusion criteria

A patient with Rheumatoid Arthritis under medical treatment with Temporomandibular Disorders

Intervention groups

The pain intensity of patients suffering from Rheumatoid Arthritis with Temporomandibular Disorders will be evaluated using a Numerical Analog Scale. Then the necessary "self-care" training will be given. 2 months later, the patient will be examined again, similar to the first session, and the symptoms will be recorded.

Main outcome variables

Temporomandibular Disorders

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221113056489N1**

Registration date: **2022-11-19, 1401/08/28**

Registration timing: **registered_while_recruiting**

Last update: **2022-11-19, 1401/08/28**

Update count: **0**

Registration date

2022-11-19, 1401/08/28

Registrant information

Name

hosna bahrami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3429 0450

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-19, 1401/08/28

Expected recruitment end date

2023-02-17, 1401/11/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of self-care in improving the symptoms of Temporomandibular Disorders in drug-treated Rheumatoid Arthritis patients

Public title

The effect of Self-care in improving symptoms of Temporomandibular Disorders in Rheumatoid Arthritis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with Rheumatoid Arthritis under anti-rheumatoid drug treatment with Temporomandibular Disorder No previous treatment for Temporomandibular Disorders

Exclusion criteria:

History of jaw trauma History of head, mouth and neck neoplasia History of maxillofacial surgery Changing the therapeutic dose of Rheumatoid Arthritis during the follow-up period

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shcool of Dentistry, Tehran Univrsity of Medical Sciences

Street address

School of Dentistry, Tehran University of Medical Sciences, North Karegar St., Enghelab Sq., Tehran.

City

Tehran

Province

Tehran

Postal code

1439955991

Approval date

2022-05-28, 1401/03/07

Ethics committee reference number

IR. TUMS.DENTISTRY.REC.1401.034

Health conditions studied

1

Description of health condition studied

Temporomandibular joint Disorders

ICD-10 code

K07.6

ICD-10 code description

Temporomandibular joint-pain-dysfunction syndrome

Primary outcomes

1

Description

Temporomandibular Disorders

Timepoint

Measuring symptoms of Temporomandibular Disorders at the beginning of the study (before the start of the intervention) and 2 months after self-care training.

Method of measurement

Numerical Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In Rheumatoid Arthritis patients under drug treatment, the symptoms of Temporomandibular Disorders will be examined by a trained examiner, and the diagnosis of Temporomandibular Disorders will be confirmed with the criteria of the RDC-TMD questionnaire, and the severity of dysfunction will be recorded based on the Helkimo clinical criteria. Patients are then asked to rate the pain intensity on a scale of 0 to 10, where 0 represents no pain and 10 represents maximum pain. After recording symptoms, the necessary "self-care" training will be given in the form of a short seminar, along with skills training provided through demonstrations, exercises between sessions, and structured feedback during sessions and phone calls. Self-care includes: education (about the socio-biology model of TMD, chronic pain, multifaceted aspects of the cause of TMD, management methods, and the logic of self-management), bilateral chewing, limitation of mouth opening (opening the mouth within the range of the patient's pain threshold), diet control (avoid eating hard food), yawn control (opposite pressure on the back of both hands under the chin), thermal modalities (use of moist heat (twice a day for 20 minutes each time) and ice compresses) 1 time and 10 minutes each time) alone or together), massage therapy (touching and caressing the muscles along them), controlling parafunctional behaviors (putting their tongue behind the front teeth of the upper jaw, such as when say "N" and then close your mouth and when the lower jaw was in a resting position, leave a few millimeters of space between the occlusion surfaces of the upper and lower teeth while the lips are slightly in

contact with each other (free space) (Patients will be instructed to maintain this relaxed position at all times at rest, except when eating or talking and to avoid involuntary muscle contraction with teeth in central occlusion). Then two weeks later, by phone, the patient will be monitored to ensure that the training is done correctly, and 2 months later, an examination will be done again, similar to the first session, and the severity of the symptoms will be recorded.

Category

Treatment - Other

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

Rheumatologist office

Full name of responsible person

Dr Tahere Faezi

Street address

Third floor, No. 58, Ziba St, Shariati St

City

Tehran

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

Tehran University of Medical Sciences

Full name of responsible person

Dr. Zahra Khorshidi

Street address

Research Center of School of Dentistry, Tehran
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1417653761

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stat@tums.ac.ir

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

Yes

Title of funding source

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Hosna Bahrami

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Faculty of Dentistry, Tehran University of Medical
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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Hosna Bahrami

Position

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Latest degree

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Other areas of specialty/work

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

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Position

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Latest degree

Specialist

Other areas of specialty/work

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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is 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

After deidentifying the patient's demographic information, the results obtained after the treatment can be shared

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions will be available

Under which criteria data/document could be used

After deidentifying the patient's demographic information, the results obtained after the treatment can be shared

From where data/document is obtainable

Faculty of Dentistry, Tehran University of Medical Sciences Hosna Bahrami 09186796325
bahrami.h1994@gmail.com

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

The access period starts 12 months after receiving the request

Comments