Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of dry needling and sham dry needling effectiveness on pain, range of motion and pressure pain threshold in patients with temporomandibular joint dysfunction after dental procedure

Protocol summary

Study aim

Determining the effectiveness of dry needling on myofascial pain of temporomandibular joint as well as range of motion in patients with mobility impairment after dentistry

Design

The randomized control trial has a control group with a parallel double-blind randomized group, on 56 patients that will use the block balanced randomization method.

Settings and conduct

The study in the Nafis physiotherapy clinic, after randomization and collection of initial information, will be performed by dry needling in the intervention group and sham dry needling in the control group in two sessions with an interval of one week.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Men and women 20-50 years old. One week or a months interval from the onset of symptoms and limited range of motion following a visit to the dentist with or without medication. Not performing physiotherapy on the head and neck for the past 12 months. No scar tissue, infection, wound or inflammation on trigger point area. Do not use addictive substances and alcohol due to rising pain threshold. Restriction of mouth opening less than 30 mm or pain with Numeric Rating Scale above 3. Exclusion criteria:Both side pain. History of clenching while sleeping or night guard using. Temporomandibular joint (TMJ) degenerative disease. Inflammation in mouth, History of TMJ or dental surgery. History of systemic or metabolic disorders, such as metabolic syndrome Rheumatoid arthritis, atypical fascial pain, neuralgia and fibromyalgia. Instability in chewing structures. Orthodontic treatment. Anticoagulant therapy. Pregnancy

Intervention groups

The intervention group is treated with dry needling therapy by a second physiotherapist in the master, temporalis, internal and external pterygoids muscles. People in the placebo group are also subjected to sham dry needling.

Main outcome variables

Range of motion, pain, pressure pain threshold

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200927048859N1**
Registration date: **2021-11-23, 1400/09/02**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-23, 1400/09/02**
Update count: **0**

Registration date

2021-11-23, 1400/09/02

Registrant information

Name

Nafiseh Zekri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3355 5455

Email address

nafiseh_zekri@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of dry needling and sham dry needling effectiveness on pain, range of motion and pressure pain threshold in patients with temporomandibular joint dysfunction after dental procedure

Public title
Evaluation of dry needling effectiveness on temporomandibular joint pain and range of motion
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Men and women 20-50 years old. Pain and range of motion limitation on one side of the temporomandibular joint who visit the dentist in the past month or a week. One week interval from the onset of symptoms and limited range of motion following a visit to the dentist with or without medication. Not performing physiotherapy on the head and neck for the past 12 months. No scar tissue, infection, wound or inflammation on trigger point area. Do not use addictive substances and alcohol due to rising pain threshold. Restriction of mouth opening less than 30 mm or pain with Numeric Rating Scale above 3
Exclusion criteria:
Both side pain History of clenching while sleeping or night guard using Temporomandibular joint (TMJ) degenerative disease Inflammation in mouth History of TMJ or dental surgery History of systemic or metabolic disorders, such as metabolic syndrome Rheumatoid arthritis, atypical fascial pain, neuralgia and fibromyalgia Instability in chewing structures Orthodontic treatment Anticoagulant therapy Pregnancy
Age
From **20 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **52**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization process will be done through closed envelopes and block balanced randomization method. First of all, the first physiotherapist considers all possible aabb arrangements and using a random number table, randomly selects 10 blocks and writes their components one after the other. Each of these components will then be placed in a sealed envelope and numbers 1 to 52 will be recorded on the envelope. Since the therapist is not aware of how the groups are assigned until the intervention, the important feature of allocation concealment is observed in this study. On the day of the intervention, the first physiotherapist choose the envelopes one by one and based on that, places the patients in the intervention group and Placebo.
Blinding (investigator's opinion)
Double blinded
Blinding description
The first physiotherapist is blind to the grouping of patients and the second physiotherapist is blind to the data obtained from the assessments of each patient performed by the first physiotherapist. The patient is also blind to which group he or she belongs to. In the control group, a sharp needle-shaped plastic shield is used so that the patient can only feel the sharp object. It should be noted that the patient's eyes are covered in both groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Qom University of Medical Sciences
Street address
No.11, Shahid Akhlaghi St, Sepah Sq, Jomhouri St, Qom, Iran
City
Qom
Province
Ghoum
Postal code
3716699845
Approval date
2021-01-26, 1399/11/07
Ethics committee reference number
IR.MUQ.REC.1399.266

Health conditions studied

1

Description of health condition studied
Pain and temporomandibular dysfunction after dental procedure
ICD-10 code
M26.6

ICD-10 code description
Temporomandibular joint disorders

Primary outcomes

1

Description
Pain with Numeric Rating Scale
Timepoint
At the beginning of the study, one week and two weeks after the start of the intervention
Method of measurement
Numeric Rating Scale; The 11-point numeric scale ranges from '0' representing one pain extreme (e.g. “no pain”) to '10' representing the other pain extreme (e.g. “pain as bad as you can imagine” or “worst pain imaginable”).

2

Description
Range of motion of temporomandibular joint
Timepoint
At the beginning of the study, one week and two weeks after the start of the intervention
Method of measurement
goniometer

3

Description
Evaluation of sensitivity of trigger points
Timepoint
At the beginning of the study, one week and two weeks after the start of the intervention
Method of measurement
Digital pressure algometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: They are treated with dry needling on masseter, temporalis, internal and external pterygoid muscles. Initially, by touching and pressing the therapist's hand on each muscle, the most sensitive point to touch is found and targeted with a needle. In this way, the special needles enter this sensitive part of the muscle and remain in the muscle for 20 minutes with infrared heat. At first, the patient's eyes are covered with wet cotton so that the infrared light does not bother and the patient is also blind to the intervention.
Category
Treatment - Other

2

Description
Control group: This group is subjected to sham dry needling. Initially, by touching and pressing the therapist's hand in all four muscles of the masseter, temporal, internal and external pterygoid, the most sensitive point to touch is found and targeted by a sharp plastic needle guide to make the patient feel sharp. And infrared heat shines on the face for 20 minutes. Initially, the patient's eyes are covered with wet cotton so that the infrared light does not bother and the patient is also blind to the intervention.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Nafis Physiotherapy clinic
Full name of responsible person
Sepideh Paybast
Street address
No.11, Iran building, Akhlaghi St. Sepah Sq. Jomhouri St
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Email
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Qom 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
Ghoum University of Medical Sciences
Full name of responsible person
Sepideh Paybast
Position
Associate professor
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
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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Measurement data and results obtained from each person can be shared.
When the data will become available and for how long
Upon completion of the study for 6 months
To whom data/document is available
Researchers on similar subjects
Under which criteria data/document could be used

To use the results of the study and citation for related studies

From where data/document is obtainable

Email researcher in charge. Dr Sepideh Paybast, sepideh.paybast@yahoo.com Physiotherapist Nafiseh Zekri, nafiseh_zekri@yahoo.com

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

Your email will be read and answered within a week.

Comments