Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Analgesic effect of ischemic compression therapy and shock wave therapy for trigger point release on temporomandibular dysfunction.

Protocol summary

Study aim
To find out the effect of ischemic compression therapy and shock wave therapy for releasing trigger point on temporomandibular dysfunction.

Design
It will be single blinding randomize clinical trial in which 45 individuals will be recruited.

Settings and conduct
This study will be conducted on Islamabad diagnostic center Faisalabad. Participants will be blinded these individuals will not known in which group they will be allocated.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Functional disorder within masticatory muscle, Complaint of acute pain and presence of joint clicking. Exclusion Criteria; If individual have diabetes, Cardiovascular problem, sensory deficient , Skin lesion, fibromyalgia and tuberculosis.

Intervention groups
Interventional groups are three. Group A will receive ischemic compression therapy, Group B will receive shock wave therapy, And group C will receive the combination effect of ischemic compression therapy and shock wave therapy.

Main outcome variables
Pain will be measure by using visual analogue scale. Functional ability will be measure by using temporomandibular dysfunction questionnaire before and after treatment

General information

Reason for update
To update the missing information

Acronym
Shock wave therapy (SWT) Ischemic compression therapy(ISC) Temporomandibular dysfunction(TMD)

IRCT registration information
IRCT registration number: **IRCT20240120060742N1**
Registration date: **2024-02-15, 1402/11/26**
Registration timing: **prospective**

Last update: **2025-02-08, 1403/11/20**
Update count: **1**

Registration date
2024-02-15, 1402/11/26

Registrant information

Name
Dr Noreen

Name of organization / entity
Madina teaching hospital

Country
Pakistan

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+92 309 8827322

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-03-18, 1402/12/28

Expected recruitment end date
2024-03-18, 1402/12/28

Actual recruitment start date
2024-06-18, 1403/03/29

Actual recruitment end date
2024-06-18, 1403/03/29

Trial completion date
2024-07-18, 1403/04/28

Scientific title
Analgesic effect of ischemic compression therapy and shock wave therapy for trigger point release on temporomandibular dysfunction.

Public title

Trigger point release on temporomandibular dysfunction by ischemic compression therapy and shock wave therapy.

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Gender both male and female. Patient age ranges from 20 to 60 year. Patients suffer from painful functional disorder within the masticatory muscles of myofascial characteristics. Chief complaint of acute pain in the joint on at least one side (duration less than 6months). Presence of joint clicking during opening that was eliminated on protrusive opening.

Exclusion criteria:

If individual have diabetes, cardiovascular problem, sensory deficient, skin lesion in thearea of trigger point, fibromyalgia and tuberculosis Pregnant women, history of fascial trauma, fracture of facial bone and facial palsy Presence of systemic disease and history of recent trauma

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **45**
More than 1 sample in each individual
Number of samples in each individual: **15**
Sample size was calculated through epi tool and according to that formula calculation there will be 45 sample size which will be further allocated into three groups by simple randomization technique. Group A will have 15 participants, Group B will have 15 participants, and Group C will have 15 participants.
Actual sample size reached: **45**
More than 1 sample in each individual
Actual sample size in each individual: **15**
randomization

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization through sealed envelope. Non-probability convenient sampling will use for the study. Groups allocation will be accomplished using simple randomization sampling technique. The participants will be recruited into this study, allocation to groups will be done by chit and draw method.

Blinding (investigator's opinion)

Single blinded

Blinding description

It is a single blind study, participants will be blinded as they will not known the treatment which they will receive.

Placebo

Not used

Assignment

Other

Other design features

sampling technique

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics committee of University of Faisalabad

Street address

No.P-11,Zeenat Block, Muslim Town1: Faisalabad, Pakistan

City

Faisalabad

Postal code

14496-14535

Approval date

2021-02-27, 1399/12/09

Ethics committee reference number

TUF/Addl Reg/A-14/119

Health conditions studied

1

Description of health condition studied

Patients who will have experience orofascial pain, pain in the muscles of mastication due to trigger points on the temporomandibular joint will include in this study.

ICD-10 code

K07.6

ICD-10 code description

Temporomandibular joint-pain-dysfunction syndrome

Primary outcomes

1

Description

Visual analogous scale.

Timepoint

At the time of enrollment, later after 3rd and last after the 6th session.

Method of measurement

1-10 Points on paper

2

Description

visual analogous scale

Timepoint

At the time of enrollment, later after 3rd and last after the 6th session.

Method of measurement

1-10 Points on paper

Secondary outcomes

1

Description
Temporomandibular dysfunction questionnaire before and after treatment.

Timepoint
At the time of enrollment, later after 3rd and last after the 6th session.

Method of measurement
Questionnaire

Intervention groups

1

Description
Interventional Group 1 will receive ischemic compression therapy. *Baseline treatment was relaxation exercise. *Fist of all patients were relaxation on treatment bed in supine line position* There were 6 treatment session in one month. *There were three consecutive treatment sessions for three days. * There was relaxation period of one week. After relaxation of one week there were three consecutive treatment session for next three days. *The time of treatment in one session was five to eight minutes per patient. In this group of treatment therapist applied compression by thumb on active trigger points for 90 seconds. *Then relax for thirty seconds. *This type of compression was applied for three time in one session and continues for three consecutive days.

Category
Treatment - Other

2

Description
Intervention group B: will receive shock wave therapy *Baseline treatment was relaxation exercises. *Patients were relaxed on the treatment bed and treated in supine line position. *Patient lying on supine line position with slightly open mouth that will reflex the jaw muscles. *After localizing and palpating the pain region shock wave was applied with energy flux density of 1500 with shock wave frequency of 2000 strokes per therapy session. *About 2000 shock wave delivered per session on the active trigger points of masseter muscles. *There was 3 session of treatment in one week. *After that there was relaxation period of one week. *After relaxation period of one week Shock wave was applied for consecutive three days. *There were 3 session of treatment in one week. There were two weeks of treatment session.

Category
Treatment - Other

3

Description
Intervention group C: Interventional Group 3 will receive the combination effect of ischemic compression therapy and shock wave therapy. *Baseline treatment was relaxation exercise. *Patients were in relaxation in supine line. *Patients received 6 session in one month, 3 days consecutive treatment after one week of relaxation again 3 days consecutive treatment.*Patients received ischemic compression therapy first. *compression of 60 second with thumb on trigger point then relaxation of 30 second.*Time of treatment was 5 to 8 minutes.*After localizing and palpating the pain region shock wave was applied with energy flux density of 1500 with shock wave frequency of 2000 strokes per therapy session. *About 2000 shock wave delivered per session on the active trigger points of masseter muscles. There were total 6 treatment sessions with one week relaxation period. There were two weeks of treatment session.*

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Islamabad diagnostic center Hospital Faisalabad/ physio fit

Full name of responsible person
Junaid Hassan

Street address
563 B, Islamabad Diagnostic Center Faisalabad Satiana Road Faisalabad

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092

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https://idc.net.pk/location/idc-faisalabad-satiana-road/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
The University of Faisalabad.

Full name of responsible person
Noreen

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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
The University of Faisalabad.
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Foreign
Category of foreign source of funding
Sponsor: country of origin
Country of origin
PK
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
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Person responsible for updating data

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noreenfatima12390@gmail.com

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
For concealing participants identity
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
No - There is not 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
Not applicable
Title and more details about the data/document
Analgesic effect of ischemic compression therapy and shock wave therapy for trigger point release on

temporomandibular dysfunction.

When the data will become available and for how long

Starting from April 2021

To whom data/document is available

This data is available for the people who are working in academic institutions.

Under which criteria data/document could be used

Data will be available to researchers with valid affiliation to any institute.

From where data/document is obtainable

noreenfatima12390@gmail.com

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

Inquirer must provide cover letter starting their reason to obtain data and a brief outlook of their research.

Comments