Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of Effects of Dry needling and High Power Laser Therapy on Clinical Signs in Females with Upper Trapezoid Muscle Active Trigger Points (a Single-Blind Randomized Clinical Trial)

Protocol summary

Study aim

Comparison of Effects of Dry Needling and High Power Laser on clinical sign in Females with Upper Trapezoid Muscle Active Trigger Points

Design

A randomized (using block randomization method), single blinded, clinical trial with two parallel group design and a sample size of 30 patients

Settings and conduct

The study is performed in rehabilitation faculty of Iran University of Medical Sciences. Then eligible participants sign informed consent form and are randomly assigned to two groups of dry needling and high power laser by blocking. Treatment and assessment is done by separate persons and assessor and analyzer of data will be kept blind. The assessor is present only at the time of assessment (before and after treatment).

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18-35 years old; 30 < pain score< 60 mm based on visual analogue scale; presence of maximum of 3 active trigger points in upper trapezius muscle; history of trigger point pain> 3 months in trapezius muscle Non inclusion criteria: history of surgery; fractures and traumatic injuries to to cervical spine; History of neurological; rheumatic and cognitive disorders; presence of symptoms of radiculopathy; malignancy; pregnancy

Intervention groups

Intervention group 1: participants received dry needle, passive stretch of upper trapezius muscle and postural correction education. Intervention group 2: participants received high-power laser, passive stretch of upper trapezius muscle and postural correction education.

Main outcome variables

Pain; pain pressure threshold; cervical lateral flexion and rotation to both; neck disability index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191208045652N2**
Registration date: **2020-03-27, 1399/01/08**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-27, 1399/01/08**
Update count: **0**

Registration date

2020-03-27, 1399/01/08

Registrant information

Name

marzieh Yassin

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 8052

Email address

m.yassin.pt@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-06-21, 1399/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of Effects of Dry needling and High Power Laser Therapy on Clinical Signs in Females with Upper Trapezoid Muscle Active Trigger Points (a Single-Blind Randomized Clinical Trial)

Public title
Effect of Dry needling and High Power Laser Therapy in treatment of Trigger Points

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Women with age range of 18-35 years The presence of pain score between 30-60 mm according to visual analogue scale during rest or movement The presence of maximum of three active trigger points in the upper trapezoid muscle The history of trigger point pain for more than three months The presence of taut band in the upper trapezoid muscle during the touch The presence of sensitive and painful points in the response to 25 N pressure The presence of referred pain pattern in the response to pressure Ability to reading and writing to Persian language

Exclusion criteria:
The history of any treatment for trigger points and steroid injections over the past 3 months The history of fibromyalgia syndrome The history of surgery and fractures in the neck The presence of symptoms of cervical disc disorders such as radiculopathy The presence of neurological diseases The history of malignancy Pregnancy Severe postural disorders such as scoliosis and kyphosis The presence of infection and skin ulcers The history of receiving anticoagulants Fear of Needle The presence of communication and cognitive impairment The history of trauma such as whiplash injuries Patient dissatisfaction to continuing treatment and assessment

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, a simple block random allocation method will be used. In order to balance the number of samples in each group, a blocking method with random sizes of 6 will be used and non-transparent envelopes will be used to hide the random assignment. It should be noted that steps are taken to create a randomization sequence by a person who is not involved in any other stage of the research

Blinding (investigator's opinion)
Single blinded

Blinding description
Assessment and treatment will be performed by two individuals. Assessor and analyzer the data are those who are unaware of the grouping and will be unaware of which group each subject belongs to. The assesor is present only at the time of assessment (before and after treatment).

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran university of medical sciences

Street address
Iran university of medical sciences, next to Milad tower, Hemmat highway

City
Tehran

Province
Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Approval date
2020-01-14, 1398/10/24

Ethics committee reference number
IR.IUMS.REC.1398.1044

Health conditions studied

1

Description of health condition studied
Upper trapezius muscle active trigger point

ICD-10 code
M70.9

ICD-10 code description
Unspecified soft tissue disorder related to use, overuse and pressure

Primary outcomes

1

Description
Pain

Timepoint
Pain before intervention, 2 days and 2 months after intervention

Method of measurement

pain with visual analogue scale

Secondary outcomes

1

Description
Pain pressure threshold
Timepoint
Before intervention, 2 days and 2 months after intervention
Method of measurement
Algometer J-Tech, USA

2

Description
Side bending & rotation range of motion
Timepoint
Before intervention, 2 days and 2 months after intervention
Method of measurement
iPhone 8 application, goniometer

3

Description
Neck Disability Index
Timepoint
Before intervention, 2 days and 2 months after intervention
Method of measurement
Persian version of Neck Disability Index questionnaire

Intervention groups

1

Description
Intervention group 1: dry needling (Dang bang South Korea, 50*0.3 mm) with passive stretching and posture correction education based on pamphlet during 5 sessions, 2 times a week, for 3 weeks.
Category
Rehabilitation

2

Description
Intervention group 2: High power laser (New Age, Italy) with wavelength of 1064 nm, power 14 W, frequency 100 Hz with passive stretching and posture correction education based on pamphlet during 5 sessions, 2 times a week, for 3 weeks.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Physiotherapy clinic of Rehabilitation Faculty of Iran University of Medical Sciences
Full name of responsible person
Marzieh Yassin
Street address
Faculty of Rehabilitation; Iran University of Medical Sciences; Madadkaran street, Shahid Shahnazari street, Madar square, Mirdamad boulevard
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2

Recruitment center
Name of recruitment center
Golestan Dormitory of Iran University of Medical Sciences
Full name of responsible person
Marzieh Yassin
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Seyed Abbas Motevalian
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motevalian.a@iums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Azize Prandnia

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Marzieh Yassin

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Physical therapy department, Rasoul Akram hospital, Niayesh street, Sattarkhan street

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Marzieh Yassin

Position

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Latest degree

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Other areas of specialty/work

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Not applicable

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

Title and more details about the data/document

All data can be shared after unidentified people

When the data will become available and for how long

starting accessibility 6 months after printing results

To whom data/document is available

The information is accessible to all researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Use of data is only possible by mentioning the name and organizational affiliation of the correspond and co-author of the project and the published article.

From where data/document is obtainable

Connect to Azize Parandnia by email: azize.parande@gmail.com

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

If information is used in scientific and therapeutic activities, information is provided as soon as possible.

Comments