

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

The effects of myofascial trigger points release of longus colli muscle on pain and range of motion in patients with neck pain

Protocol summary

Study aim

Investigation of the immediate effect of releasing trigger points of the longus colli muscle and placebo ultrasound on pain, range of motion of neck pain joints in people with non-specific neck pain

Design

A clinical trial with the control group, parallel groups, randomized, phase 2 on 50 patients. The rand function of Excel software was used for randomization.

Settings and conduct

This research project will be carried out by a physiotherapist in the physiotherapy clinic of the comprehensive center and, if possible, in the private physiotherapy center. For this purpose, after the patients visit the above clinic, a list of people who meet the inclusion criteria will be prepared, and the studied people will be interviewed. People who meet the study entry criteria will be selected non-randomly. After filling out the consent form, they will be randomly assigned (sealed envelope) to two groups, including 1) the trigger point release group of longus colli muscle and 2) the control group receiving placebo treatment. Randomization is done in a blocked manner.

Participants/Inclusion and exclusion criteria

Chronic neck patients over the age of 18 who do not have a history of particular diseases and red-flag symptoms.

Intervention groups

In this study, the myofascial release technique of the longus colli muscle is performed manually while the patient is lying on her back.

Main outcome variables

pain and range of motion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230212057390N2**

Registration date: **2023-10-07, 1402/07/15**

Registration timing: **prospective**

Last update: **2023-10-07, 1402/07/15**

Update count: **0**

Registration date

2023-10-07, 1402/07/15

Registrant information

Name

Majid Shahbazi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3884 6710

Email address

shahbazim2@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2024-09-21, 1403/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of myofascial trigger points release of longus colli muscle on pain and range of motion in patients with neck pain

Public title

The myofascial trigger points release of longus colli muscle in neck pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The patient shows at least mild disability, number 5-14, based on the Neck Disability Index (NDI) scale. Complaints of chronic neck pain (more than 3 months) When entering the study, patients should have at least 3 pain based on the VAS scale when performing neck movements. Patients have not used painkillers 24 hours before the tests. Being over 18 years old

Exclusion criteria:

Observation of any serious pathology such as specific neck pain and red flag symptoms such as cervical spine tumor, whiplash injury, neck fracture, and previous cervical spine surgery were excluded from the study. Patients with a recent cerebrovascular stroke, myocardial infarction, chronic lung or kidney disease, serious medical or psychiatric conditions, or unstable dementia were also excluded. Patients who do not want to participate in the study for any reason.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were allocated in the experiment, half assigned to the control group (n = 25) and half to the experimental group (n = 25) using the block randomization method. The randomization was performed by an investigator who was not involved with participant intervention.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical

Sciences

Street address

Department of Physical Therapy, School of Paramedical and Rehabilitation Sciences, University campus, Azadi square, Mashhad, Iran.

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948964

Approval date

2023-03-04, 1401/12/13

Ethics committee reference number

IR.MUMS.FHMPM.REC.1401.203

Health conditions studied

1

Description of health condition studied

neck pain

ICD-10 code

S16

ICD-10 code description

Injury of muscle, fascia and tendon at neck level

Primary outcomes

1

Description

Measurement of pain and range of motion

Timepoint

After the patient referred to the physical therapy center

Method of measurement

Pain is measured with a visual analog scale (VAS) and range of motion with a goniometer.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The method of performing the myofascial release technique: For manual muscle release, while the patient is lying on his back, the head is slightly extended to provide sufficient access to the anterior region of the neck. The back of the index, middle, and ring fingers are placed under the sternocleidomastoid muscle and gently lifted. In contrast, the pads of the fingers are placed on the anterior surface of the transverse processes. Then, the fingers go back and towards the anterior cervical spine. It slides and sits directly on it. The longus colli muscle at that point is covered only by subcutaneous tissue and skin. In this case, the back of the fingers is placed in front of the trachea, and the tips of the fingers are placed under the

carotid and sternocleidomastoid sheaths. Then, the manual release is done with a deep massage of the longus colli muscle. The release includes gentle massage of the muscle in a cranial-caudal way. The fingers are gently moved over the anterior surface of the cervical seals and transverse processes while the patient performs mild flexion-extension movements of the neck [9]. Another method of touching the trigger points in the longus colli muscle can be felt by placing the examining finger along the lateral border of the trachea between the sternocleidomastoid muscle and the thyroid cartilage, and by separating the muscle from the adjacent trachea, gently rocking it forward. When the finger hits the vertebral column, the area is examined for trigger points by cross-fiber palpation [8].

Category

Rehabilitation

2

Description

Control group: Conducting ultrasound of the anterior neck region. The subject is informed that pulsed ultrasound will be used. They should not feel any heat or pain. Since this is a dummy method, such an adjustment will not make any real difference. Ultrasound lotion is applied on the front of the neck between the sternocleidomastoid muscle and trachea, and the ultrasound head is moved slowly on the front of the neck in the area of trigger points for 2 minutes. The device's timer will alert the therapist when 2 minutes have passed.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Physiotherapy clinic of the Comprehensive Center of Mashhad University of Medical Sciences and, if p

Full name of responsible person

Majid Shahbazi

Street address

Department of Physical Therapy, School of Paramedical and Rehabilitation Sciences, University campus, Azadi square, Mashhad, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Majid Shahbazi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

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Name of organization / entity

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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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

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

Part of the data, such as the information related to the main outcome, 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

It will be available for researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Access is possible after a written request to Mashhad University of Medical Sciences and after examination.

From where data/document is obtainable

Dr. Majid Shahbazi - Mashhad University of Sciences - Faculty of Paramedical Sciences - Department of Physiotherapy - 09155228949

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

Send a written request to the Department of Physiotherapy of the University of Medical Sciences and an answer will be given after review. It will take about 1 month.

Comments