

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparison of aerobic training and acupuncture and acupuncture alone in treatment of neck myofascial pain syndrome

Protocol summary

Summary

(1) Objective: The aim of this study is to compare aerobic training and acupuncture with acupuncture alone in treatment of neck myofascial pain syndrome. (2) Design: In this study, 60 patients with neck myofascial pain syndrome referring to physical medicine and rehabilitation clinics will be included in the study after qualifying the inclusion and exclusion criteria and obtaining the informed consent. (3) Setting and conduct: Patients will be randomly divided to groups of thirty. For randomization we will use computerized randomization with Excel software. Inclusion criteria are pain in the neck and shoulder regions for more than two months, pain in more than 3 other trigger points in muscles around the neck and shoulder regions and willingness to participate in the study. Exclusion criteria are severe osteoarthritis of the knees or lumbosacral problems which prohibit the patient from doing aerobic training, systemic diseases which prohibit the patients for acupuncture or aerobic training, known allergy to metals, pregnancy and malignancies. (4) Interventions: Before initiating the study pain severity will be recorded as VAS score. Quality of life and neck disability questionnaire will be filled out too. Pain threshold in trigger points will be determined using a digital algometer device and a 4kg/cm² pressure. This will be done three times with a 10 seconds interval. In control group, acupuncture will be performed for 10 sections weekly. In intervention group, in addition to acupuncture, in each section, aerobic training will be administered for 30 - 45 minutes using treadmill and exercise bicycle. (5) Main outcome measures: VAS score, quality of life and neck disability questionnaire scores and pain threshold will be evaluated before, after and one month after completing the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201509264641N11**

Registration date: **2015-10-27, 1394/08/05**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-10-27, 1394/08/05

Registrant information

Name

Bina Eftekharsadat

Name of organization / entity

Tabriz university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1330 3193

Email address

binasadat@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2015-11-22, 1394/09/01

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of aerobic training and acupuncture and

acupuncture alone in treatment of neck myofascial pain syndrome

Public title

Study of adding aerobic training to acupuncture in treatment of neck myofascial pain syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Pain in the neck and shoulder regions for more than two months; pain in more than 3 other trigger points in muscles around the neck and shoulder regions; willingness to participate in the study. Exclusion criteria: Severe radiculopathy based on radiculopathy symptoms such as weakness, radicular pain, decreased reflexes or upper limb sensory loss and a positive spurling test; cervical discopathy approved with MRI; severe osteoarthritis of the knees or lumbosacral problems which prohibit the patient from doing aerobic training; systemic diseases which prohibit the patients for acupuncture or aerobic training; known allergy to metals; pregnancy; malignancies.

Age

From **20 years** old to **45 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

Street address

Ethics committee, Tabriz University of Medical Sciences, Golgasht Street, Azadi Street, Tabriz

City

Tabriz

Postal code**Approval date**

2014-07-10, 1393/04/19

Ethics committee reference number

92194

Health conditions studied**1****Description of health condition studied**

Cervicalgia

ICD-10 code

M54.2

ICD-10 code description

Cervicalgia

Primary outcomes**1****Description**

Pain

Timepoint

Before study, after study, one month after study

Method of measurement

By using Visual Analogue Scale (VAS)

Secondary outcomes**1****Description**

Quality of life

Timepoint

Before study, after study, one month after study

Method of measurement

By using quality of life questionnaire

2**Description**

Neck functional status

Timepoint

Before study, after study, one month after study

Method of measurement

By using neck disability index questionnaire

Intervention groups**1****Description**

In control group, acupuncture will be performed for 10 sections weekly.

Category

Treatment - Devices

2**Description**

In intervention group, in addition to acupuncture, in each

section, aerobic training will be administered for 30 - 45 minutes using treadmill and exercise bicycle

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Dr. Bina Eftekharsadat

Street address

Department of Physical Medicine and rehabilitation,
Imam Reza Hospital, Daneshgah Square, Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of
Medical Sciences

Full name of responsible person

Dr. Hasan Soleimanpour

Street address

Vice chancellor for research, Tabriz University of
Medical Sciences, Daneshgah square, Tabriz

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Tabriz University of Medical
Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Elmira Pourjafari

Position

Physical medicine and rehabilitation resident

Other areas of specialty/work

Street address

Department of Physical Medicine and rehabilitation,
Imam Reza Hospital, Daneshgah Square, Tabriz

City

Tabriz

Postal code

Phone

+98 41 3337 3967

Fax

Email

Elishan02@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Bina Eftekharsadat

Position

Associate professor of Physical Medicine &
rehabilitation

Other areas of specialty/work

Street address

Department of Physical Medicine and rehabilitation,
Imam Reza Hospital, Daneshgah Square, Tabriz

City

Tabriz

Postal code

Phone

+98 41333361928

Fax

Email

binasadat@tbzmed.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Elmira Pourjafari

Position

Physical medicine and rehabilitation resident

Other areas of specialty/work

Street address

Department of Physical Medicine and rehabilitation,
Imam Reza Hospital, Daneshgah Square, Tabriz

City

Tabriz

Postal code

Phone

+98 41 3337 3967

Fax

Email

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty