

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Biofeedback therapy effect on myofacial neck pain

Protocol summary

Study aim

Determination of the therapeutic effect of EMG biofeedback in cervical pain in patients with myopathic pain syndrome

Design

Clinical practice has three intervention groups of 20 people, based on treatment type, single blinded and randomized A random sequence is created using the random numbers table and created by the statistician and will be available to him.

Settings and conduct

60 patients wer divided into three groups, at Tabriz Medical School: biofeedback(BF), conventional physical therapy(PT), biofeedback-physiotherapy. For PT sessions, we will use physical methods such as hot pack, ultrasound, and electric nervous electrical stimulation, and then we will train the tensile and para-spinal cervical muscles and trapezius muscle stomach muscles. In BF sessions, patients learn how to rest the upper trapezius muscles through visual feedback by using an electromagnetic resting device. Measurement is done by one of the researchers, which leads to the allocation of blind groups

Participants/Inclusion and exclusion criteria

1)History of neck pain in last 3 month 2)Myofascial trigger points in upper trapezius muscle 3)Informed consent 4)absece of neck truma 5)absence of neck degenrative disorders 6)absence of neck radiculopathy 7)absence of Peripheral neuropathy 8)age between 18-65

Intervention groups

In Group 1 at PT sessions, we will use physical methods like hot pack, ultrasound, and trans-cutaneous electrical nerve stimulation , and then we will train the tensile and para-spinal cervical muscles and trapezius muscle. In Group 2 at BF sessions, patients learn how to put upper superficial muscles in rest through visual feedback using a superficial electromyographic device. In Group 3, Those patients in biofeedback-physiotherapy group would receive both biofeedback and physiotherapy treatment.

Main outcome variables

Neck pain, Neck disability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100827004641N13**

Registration date: **2018-12-09, 1397/09/18**

Registration timing: **retrospective**

Last update: **2018-12-09, 1397/09/18**

Update count: **0**

Registration date

2018-12-09, 1397/09/18

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

Expected recruitment start date

2018-02-01, 1396/11/12

Expected recruitment end date

2018-03-30, 1397/01/10

Actual recruitment start date

2018-02-01, 1396/11/12

Actual recruitment end date

2018-06-20, 1397/03/30

Trial completion date

2018-06-20, 1397/03/30

Scientific title

Biofeedback therapy effect on myofacial neck pain

Public title

Biofeedback in myofacial neck pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

- 1) To have a history of neck pain in last 3 month
- 2) To have myofascial trigger points in upper trapezius muscle
- 3) To participate in the study with an Informed consent
- 4) To be aged between 18-65

Exclusion criteria:

- 1) To have a history of neck trauma
- 2) To have neck degenerative disorders
- 3) To have neck radiculopathy
- 4) To have Peripheral neuropathy

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients who are eligible for inclusion in the study will be randomly assigned to three treatment groups using a randomized, randomized, randomized trial. In order to execute the randomization process to create random sequences, hide random effects and execute the random allocation process, this will be done: Run the randomization process. A random sequence is created using the random numbers table and created by the statistician and will be available to him. The doctor will evaluate it in terms of entry and exit criteria based on the order in which the participants enter the study, and if the referral is eligible for inclusion in the study, he will be evaluated prior to the intervention and will record the relevant information. The patient will then undergo a washout period. Two hours before the next referral to the patient immediately after the wash out period and for intervention, the doctor will contact the patient by telephone or text message and will ask him / her about the random allocation of the participant to the specific group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients in each group are evaluated by an assistant physician who is not aware of the type of intervention, before the intervention, one week after the intervention and two months after the intervention, and the degree of variation between the three groups will be compared at

different times. It should be noted that all interventions are carried out by persistent individuals (physicians and physicians).

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

EmamReza hospital, Golbad ave.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2018-09-24, 1397/07/02

Ethics committee reference number

IR.TBZMED.REC.1397.534

Health conditions studied

1

Description of health condition studied

Myofacial neck pain

ICD-10 code

M62.4

ICD-10 code description

Contracture of muscle

Primary outcomes

1

Description

Neck pain

Timepoint

Before therapy and one month after therapy and three months after therapy

Method of measurement

VAS questionnaire

Secondary outcomes

1

Description

Neck disability

Timepoint

Before therapy and one month after therapy

Method of measurement

NDI questionnaire

Intervention groups

1

Description

Intervention group 1: In biofeedback sessions, patients learn how to relax their upper trapezius muscle through visual computerized feedback by electrical electromyography device (surface EMG). In case of muscle weakness, strengthening and endurance training sessions would be held for each individual patient using EMG-biofeedback system. Patients have 10 sessions of therapy.

Category

Rehabilitation

2

Description

Intervention group 2: For physiotherapy sessions, we will use physical modalities such as hot pack, ultrasound and trans cutaneous electrical nerve stimulation (TENS) followed by cervical and shoulder range of motion and stretch exercises for cervical paraspinalis and upper trapezius muscle.

Category

Rehabilitation

3

Description

Intervention group 3: Those patients in biofeedback-physiotherapy group would receive both biofeedback and physiotherapy treatment.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital rehabilitation clinic

Full name of responsible person

Doctor Alireza Pishgahi

Street address

Imam Reza hospital, Golgasht Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Abolghasem Jouyban

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Alireza Pishgahi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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Physical Medicine and Rehabilitation Research Center of Tabriz, Imam Reza hospital, Golgasht st.

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Web page address**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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

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