

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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 truma
- 2)To have neck degenrative 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

Befor therapy and one mounth after therapy and three mounths 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

##### **City**

Tabriz

##### **Province**

East Azarbaijan

##### **Postal code**

5166614766

#### **Phone**

+98 41 3337 3967

#### **Email**

Maryam\_najafie@yahoo.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Tabriz University of Medical Sciences

##### **Full name of responsible person**

Abolghasem Jouyban

##### **Street address**

Tabriz University of Medical Sciences, Attar neishabouri avenue

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East Azarbaijan

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##### **Phone**

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##### **Email**

Maryam\_najafie@yahoo.com

#### **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

##### **Street address**

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

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Maryam\_najafie@yahoo.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Maryam\_najafie@yahoo.com

**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