Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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+98 41 1330 3193

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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 commitee 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
Befor therapy and one mounth 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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Phone
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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
Street address
Tabriz University of Medical Sciences, Attar neishabouri avenue
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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
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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
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