Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

To compare the shoulder girdle exercises with and without electromyographic biofeedback on the electromyography activity of the shoulder girdle muscles in individuals with primary impingement syndrome: A randomized clinical trial

Protocol summary

Study aim
Determining the effect of exercises of shoulder girdle muscles with EMG biofeedback on electrical activity of this muscles

Design
controlled, parallel-group, single-blind, randomized clinical trial on 45 patients, Permutated block randomization

Settings and conduct
Study will be conducted at the Neuromuscular Rehabilitation Research Center of Semnan University of Medical Sciences People with primary shoulder impingement syndrome are randomly assigned to one of three intervention and control groups The evaluator will be blinded to allocation

Participants/Inclusion and exclusion criteria
inclusion criteria: age 18 to 35 normal BMI onset of shoulder pain less than a year pain in the anterior or lateral part of upper arm VAS <4 positive at least 3 (painful arc during flexion or abduction Neer Kennedy-Hawkins Jobe tests pain during resisted movement of external rotation or abduction) affected side is dominant continuous pain for at least one week in six months Past no limitation in shoulder ROM exclusion criteria: simultaneous pain in both shoulders positive drop arm test sulcus sign history of heart disease pregnancy person cannot work with EMG biofeedback other orthopedic diseases and surgery fracture dislocation subluxation in the upper quadrant of skeleton Systemic and neurological diseases use of corticosteroid drugs and rehabilitation of neck and shoulder girdle in last 6 months and any drug in last two weeks

Intervention groups
All three groups receive routine physiotherapy The intervention group perform specific progressive resistive exercises of external rotator muscles of arm and stabilizer muscles of this movement with EMG biofeedback, at the end they receive cold pack. first control group perform the same exercises without feedback and second control group only receive routine physiotherapy

Main outcome variables
normalized muscle electrical activity; pain; DASH questionnaire score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240313061278N1**
Registration date: **2024-04-03, 1403/01/15**
Registration timing: **prospective**

Last update: **2024-04-03, 1403/01/15**
Update count: **0**

Registration date
2024-04-03, 1403/01/15

Registrant information
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-04-20, 1403/02/01
Expected recruitment end date
2024-07-22, 1403/05/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
To compare the shoulder girdle exercises with and without electromyographic biofeedback on the electromyography activity of the shoulder girdle muscles in individuals with primary impingement syndrome: A randomized clinical trial

Public title
The effect of electromyographic biofeedback on the electromyographic activity of the shoulder girdle muscles in primary impingement syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Onset of shoulder pain less than a year ago Pain in the anterior or lateral part of the upper arm Shoulder pain in the range of VAS less than 4 (1 to 3) Positiveness of at least 3 of the following: painful arch during flexion or abduction movements - positive Neer test - positive Kennedy-Hawkins test - positive Jobe test - pain during resisted movement of external rotation or abduction The involved side is the dominant side of the person Persistent pain for at least one week in the past six months Without limitation in shoulder range of motion Age between 18 and 35 years Normal BMI (18.5 to 24.9)
Exclusion criteria:
Pain in both shoulders at the same time Positive drop arm test for complete rotator cuff tear Instability or hypermobility of the glenohumeral joint (sulcus sign) History of heart disease pregnancy Person cannot work with electromyographic biofeedback Other orthopedic diseases in the upper quadrant of the skeleton Systemic diseases Neurological diseases Surgery, fracture, dislocation or subluxation in the upper quadrant of the skeleton People who have taken corticosteroid drugs in the last six months People who have taken any medicine in the previous two weeks People who have received cervical or shoulder girdle rehabilitation in the last six months
Age
From **18 years** old to **35 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized
Randomization description
The sample size in each group is 15 people (45 people in total). Permuted block randomization is used for randomization. For this, we use blocks of six in the following order. In each block, a means the intervention group (EMG biofeedback with exercise and routine physiotherapy), b (exercise therapy along with routine physiotherapy) and c (routine physiotherapy alone) means the control groups. First, a number is assigned to each of the blocks (aabbcc cabbac abcabc bacbac cbaabc bbaacc ccaabb aaccbb ccbbaa) randomly from 1 to 9, then people are placed in the blocks from block one and from the left. and based on the letter (a, b, and c) that is chosen for each person, the person enters the intervention or control groups. The participants, the therapist and the evaluator will be unaware of the grouping. To implement the generated random sequence, the method of hiding the box or coded cans is used. In this method, the cans will be numbered based on a random sequence, and inside the boxes, the intended intervention will be provided to the therapist with a sheet on which random allocation is written, with the condition that the boxes are sealed and completely confidential. and the therapist will assign them to the intervention and control groups based on the order of arrival of the patients.
Blinding (investigator's opinion)
Single blinded
Blinding description
A physiotherapist will be in charge of the treatment process and another physiotherapist will evaluate the desired variables. For this reason, the study will be a single-blind study from the evaluator.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Semnan University Of Medical Sciences and Health Services
Street address
Basij Blvd, Semnan University of Medical Sciences
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Approval date

2024-03-11, 1402/12/21

Ethics committee reference number

IR.SEMUMS.REC.1402.312

Health conditions studied

1

Description of health condition studied

Primary shoulder impingement syndrome

ICD-10 code

M75.4

ICD-10 code description

Impingement syndrome of shoulder

Primary outcomes

1

Description

Normalized muscle electrical activity

Timepoint

Before and After of the Intervention

Method of measurement

Surface EMG

Secondary outcomes

1

Description

Pain

Timepoint

Before and After of the Intervention

Method of measurement

Visual analogue scale (VAS)

2

Description

Functional disability

Timepoint

Before and After of the Intervention

Method of measurement

The disabilities of the arm, shoulder and hand (DASH) questionnaire

Intervention groups

1

Description

Intervention group: Treatment in the intervention group (15 people) includes 24 sessions (8 weeks, 3 days a week, every other day). At the beginning of the treatment sessions, 20 minutes of hot pack, 20 minutes of conventional transcutaneous electrical nerve stimulation (TENS) and 5 minutes of 1 MHz and 1.5 intensity ultrasound are performed. Then, before doing the exercises, the people of this group perform upper limb cycling exercises without resistance for 5 minutes, then, based on the standard shoulder exercise protocol, progressive resistance exercises of the external rotator muscles of the arm (infraspinatus and teres minor) including external rotation exercises of the arm in the neutral position, 45 degrees of abduction, 90 degrees of abduction and in the weight bearing position and progressive resistance exercises of the stabilizer muscles of the movement of the external rotation of the arm (middle and lower trapezius) including scapular retraction and T and Y exercises with EMG biofeedback and under external resistance by Theraband. The amount of resistance applied by Theraband (Theraband color) is increased and determined as a percentage of the maximal voluntary isometric contraction (MVIC) of each muscle according to the desired week from 50% to 80% of MVIC. This resistance is determined weekly. Also, the exercises are done in 10 repetition in each set, and the number of sets increases from 2 sets to 3 sets according to the desired week. Also, oscillation is added to the end of the exercises to apply more resistance along with the progress of the exercises. At the end, a cold pack is used for 10 minutes to prevention of pain and inflammation after the exercises. Range of motion exercises are repeated ten times a day and stretching exercises are performed five times a day.

Category

Treatment - Devices

2

Description

Control group: The treatment in the first control group (15 people) includes 24 sessions (8 weeks, 3 days a week, every other day). The treatment in this group will be the same as the intervention group, with the difference that this group will perform exercises without EMG biofeedback. exercise resistance is also determined by Theraband and based on the percentage of MVIC at the beginning of each week (Theraband color), then the people of this group perform the exercises with the determined Theraband and without EMG biofeedback.

Category

N/A

3

Description

Control group: The treatment in the second control group (15 people) includes 24 sessions (8 weeks, 3 days a week, every other day). In this group, only routine physiotherapy including 20 minutes of hot pack, 20 minutes of conventional transcutaneous electrical nerve stimulation (TENS) and 5 minutes of 1 MHz and 1.5 intensity ultrasound is performed, and this group does not perform therapeutic exercise intervention. At the end of the study, the results will be evaluated and compared with other groups.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Neuromuscular Rehabilitation Research Center of Semnan University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

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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
Semnan 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
Semnan University of Medical Sciences

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Master student

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available