Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluating the efficacy of therapeutic exercises and trigger points dry needling in patients with forward head posture

Protocol summary

Study aim

The aim of this study will be to compare effectiveness of exercise therapy and and trigger points dry needling on neck and shoulder angle, pain intensity and quality of life of patients.

Design

The study is a phase 3 clinical trial that will be performed on 60 patients. Patients will be randomly assigned to two groups of exercise therapy and Dry Needling using the envelope method.

Settings and conduct

This study will be performed as a single (blindness evaluator of intervention outcome) in Besat Hospital in Hamadan.

Participants/Inclusion and exclusion criteria

Participants in the study will be patients aged 14 to 65 years with with forward head posture that will be diagnosed based on clinical criteria. comorbidity with other musculoskeletal diseases, spinal diseases, neurological and motor diseases, history of shoulder surgery and vascular diseases are the exclusion criteria.

Intervention groups

Intervention: Patients in the exercise therapy group will be under the supervision of the therapist, twice a week for 20 minutes (three stretching exercises and four strength exercises). To increase patients' resistance, all exercises are started lightly, including 2 sets of 15, and gradually the intensity, number of sets and repetition of movements will be increasing. The second group of Dry Needling trigger points (TrPs) will be performed. The neck and shoulder girdle muscles will first be evaluated by a specialist with experience in finding TrPs. Dry Needling is performing on a bed in a quiet room for 10 minutes by inserting an acupuncture needle 0.3 mm in diameter and 50 mm long into the TrPs. Needle is raised and lowered 3 to 5 times and then removed. As with the exercise therapy group, treatment sessions in this group are twice a week for 12 weeks

Main outcome variables

The outcomes of the intervention include changes in neck and shoulder angle, pain score and quality of life of patients.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151123025202N17**
Registration date: **2021-07-17, 1400/04/26**
Registration timing: **prospective**

Last update: **2021-07-17, 1400/04/26**
Update count: **0**

Registration date

2021-07-17, 1400/04/26

Registrant information

Name

Abbas Moradi

Name of organization / entity

Hamedan University of Medical Of Science

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-06, 1400/05/15

Expected recruitment end date

2022-02-04, 1400/11/15

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating the efficacy of therapeutic exercises and trigger points dry needling in patients with forward head posture

Public title
Treatment of forward head posture
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of forward head posture abnormalities according to clinical criteria Age 65-14 years
Exclusion criteria:
Comorbidity of other musculoskeletal diseases, spinal diseases, neurological and motor diseases History of shoulder surgery Vascular diseases
Age
From **14 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
We made 60 cards and write letter V on 30 for Intervention and on the other 30 letter D for the control group. Then put them inside the envelope with aluminum wrap and put in a box. At the time of patient arrival, one of the envelopes randomly will be selected and will be opened, based on selected letter V or D patients will be assigned to exercises therapy or dry needling group.The sampling process will be continues until all the cards are selected
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, the person evaluating the angle of head, neck and shoulders in the image taken by digital camera and analyzed computer software, pain score of patients with visual analog scale and quality of life of patients with SF-12 scale will be blinded regarding to intervention groups .
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Hamadan University of Medical Science
Street address
Ṣhahid Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838697
Approval date
2021-01-30, 1399/11/11
Ethics committee reference number
IR.UMSHA.REC.1399.924

Health conditions studied

1

Description of health condition studied
forward head posture
ICD-10 code
M95.9
ICD-10 code description
Acquired deformity of musculoskeletal system, unspecified

Primary outcomes

1

Description
Changes neck and shoulder angle
Timepoint
Before the intervention and at the end of week 12 of the intervention
Method of measurement
Taking a photo of the profile of the body, analysis with a computer

2

Description
Pain severity
Timepoint
Before the intervention and at the end of week 12 of the intervention
Method of measurement
Visual Analogues Scale

Secondary outcomes

1

Description
Quality of life associated with forward head posture
Timepoint
Before and 12 weeks after the intervention
Method of measurement
Questionnaire SF-12

Intervention groups

1

Description
Intervention group: The duration of treatment in this study will be 3 months (12 weeks). Exercise therapy sessions will be performed twice a week for 20 minutes under the supervision of a therapist. The exercise therapy protocol will include three stretching exercises and four strength exercises aimed at correcting the condition of the neck and shoulders position. Strength training is designed for rotator cuff activity, minor fear, infra-spinatus, scapular stabilizing muscles (upper and lower trapezius), rhomboids, and deep neck flexors. Stretching exercises are designed to stretch the shortened pectoralis minor muscles and the SCM neck muscles and the scapula lift. The exercise program is performed under the direct supervision of the therapist to ensure the correctness of the exercises. To increase patients' resistance, all exercises are started lightly, including 2 sets of 15, and gradually increase the intensity, number of sets and repetition of movements. The average duration of exercise will be 20 minutes and the exercise sequence is random.
Category
Rehabilitation

2

Description
Intervention group: For patients in the Dry Needling group of trigger points (TrPs), the neck and shoulder girdle muscles, including the trapezius, SCM, sub-occipital, scapula, scale, pectoralis major, and infra-spinatus muscles, will first be evaluated by a experienced specialist to finding TrPs. . The identified TrPs are marked for each patient in an anatomical shape. For Dry Needling, patients will be asked to lie in a comfortable bed in a quiet room for 10 minutes. Dry Needling is then performed by inserting an acupuncture needle 0.3 mm in diameter and 50 mm in length into the identified TrPs. The needle is raised and lowered for 3-5 times and then removed. As in the exercise therapy group, treatment sessions in this group will be twice a week for 12 weeks.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Hospital
Full name of responsible person
Lobat Majidi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Abbas Moradi
Position
Coach
Latest degree
Master
Other areas of specialty/work
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Assistant Professor
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Person responsible for updating data

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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