

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

The role of elbow exercises protocol in treatment of patients with lateral epicondylitis (Tennis elbow)

Protocol summary

Study aim

The main purpose of the project: • Determine the effectiveness of elbow exercise protocols in patients with lateral epicondylitis (tennis elbow)

Design

two interventional groups, community based and pragmatic, with parallel groups, randomized with Not Blinded. The number of 40 patients with chronic lateral epicondylitis from 25 to 55 years of age will be selected. Based on the four blocks, the randomly assigned positions will be divided into two groups of 20 people

Settings and conduct

In this study, we will examine the patients referring to the Deziani orthopedic clinic in Gorgan. The number of 40 patients with chronic lateral epicondylitis between the ages of 25 and 55 years was selected based on the four blocks, placed in two groups of 20 people. Study is Not blinded. In this study, the participants are fully aware of the types of treatments and type of study

Participants/Inclusion and exclusion criteria

Criteria for entering the study include the presence of lateral pain in the elbow for at least 4-6 weeks with at least 2 positive tests from the following 4 tests: 1. Lateral epicondylar tenderness 2. Elbow pain during extension of the wrist against resistance 3. Elbow pain during tough fingers 4. Elbow pain during passive flexion Non-inclusion criteria include history of trauma to the elbow, history of infected elbow surgery, infusion or physiotherapy of the affected elbow in the past 6 months.

Intervention groups

Group A: For a 4-week treatment period, meloxicam 15 mg twice daily will be combined with elbow bracelet with moderate activity. Group B: In addition to the above, the sports protocol will also be implemented.

Main outcome variables

The results of this study include improvement in pain rate, severity of specific activities and severity of routine activities.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180812040773N1**

Registration date: **2019-01-29, 1397/11/09**

Registration timing: **retrospective**

Last update: **2019-01-29, 1397/11/09**

Update count: **0**

Registration date

2019-01-29, 1397/11/09

Registrant information

Name

Behfar Taziki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3252 4635

Email address

Behfartaziki@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

2017-09-23, 1396/07/01

Actual recruitment end date

2018-04-21, 1397/02/01

Trial completion date

2018-04-21, 1397/02/01

Scientific title

The role of elbow exercises protocol in treatment of patients with lateral epicondylitis (Tennis elbow)

Public title

Role of exercise in elbow pain relief

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pain in lateral side of elbow for at least 4-6 weeks
Lateral Epicondyle Tenderness
Elbow pain Due to wrist Extension against resistance
Elbow pain Due to fingers Tight flexion
Elbow pain Due to Wrist flexion
People at least 25 years of age and up to 55 years old

Exclusion criteria:

Trauma History To Elbow
Surgical History Of Elbow Injection or physiotherapy of the affected elbow in the last 6 months
The history of systemic inflammatory diseases or neurological skin diseases
The presence of pain at the same time in the shoulder or wrists of the side or the pain of the neck
Limit of shoulder Range Of Motion
Cases of chronic underlying disease such as diabetes or rheumatologic diseases
Hard Work
Failure to fill in the questionnaire
Failure to follow this course
People under the age of 25 or over 55 years

Age

From **25 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

A total of 40 patients with chronic lateral epicondylitis between the ages of 25 and 55 will be divided into two groups of 20, based on random blocks (Block Randomization).

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Golestan University of Medical Sciences

Street address

Central Organization of Golestan University of Medical Sciences, Blvd. Hirkan, Gorgan

City

Gorgan

Province

Golestan

Postal code

4934174515

Approval date

2019-01-06, 1397/10/16

Ethics committee reference number

IR.GOUMS.REC.1397.203

Health conditions studied

1

Description of health condition studied

Lateral Epicondylitis or Tennis Elbow

ICD-10 code

M77.10

ICD-10 code description

Lateral epicondylitis, unspecified elbow

Primary outcomes

1

Description

Improvement in the amount of pain

Timepoint

All patients are followed up on a weekly basis with Telephone and will be examined by the use of the Visual Analog Scale and Tennis Elbow Function Tests before and after intervention and one month after the start of the intervention.

Method of measurement

Based On Tennis Elbow Function Test and Visual Analogue Scale

2

Description

Severity of difficulty in certain activities

Timepoint

All patients are followed up on a weekly basis with Telephone and will be examined by the use of the Visual Analogue Scale and Tennis Elbow Function Tests before and after intervention and one month after the start of the intervention.

Method of measurement

Based On Tennis Elbow Function Test and Visual Analogue Scale

3

Description

Severity of difficulty in common activities

Timepoint

All patients are followed up on a weekly basis with Telephone and will be examined by the use of the Visual Analogue Scale and Tennis Elbow Function Tests before and after intervention and one month after the start of the intervention.

Method of measurement

Based On Tennis Elbow Function Test and Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For a 4-week course of treatment, meloxicam 15 mg twice daily with an elbow brace accompanied by moderating stimulant activities such as carrying objects, writing, driving, folding, twisting screwdrivers, etc.

Category

Treatment - Drugs

2

Description

Intervention group: In addition to the above, the following protocols are implemented:1. Stretch the wrist extensor muscles: With a healthy hand, bend the wrists while the elbows are located in the prosthesis and extension. Keep this movement for 10 seconds and repeat after a little rest.2. Slow and gradually tighten the wrist for 10 seconds and repeat it in 4 to 6 sets of 10 times a day.3. Active motion of the wrist in the form of flexion, extension, deviation to the radial and ulnar of the wrist for 10 seconds and repeat it.4. MassageAll movements are repeated in 4-6 sets of 10, and during exercises, when the pain is experienced, the person stops practicing, but mild pain does not prevent the training from being interrupted.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Gorgan Dezziani clinic of Orthopaedic

Full name of responsible person

Afshin Saheb jamei

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Shahid Beheshti str

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Mohammad Reza Honarvar

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Deputy of research and technology of Golestan University of Medical Sciences, Blvd. Hirkan, Gorgan

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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

Gorgan 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

Gorgan University of Medical Sciences

Full name of responsible person

Behfar Taziki

Position

Medical Intern

Latest degree

A Level or less

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Person responsible for updating data

Contact

Name of organization / entity
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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

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

Title and more details about the data/document

In this study, all data are published after being unidentifiable, and will be available to researchers.

When the data will become available and for how long

Four months after the publication, data access is provided to researchers.

To whom data/document is available

Researchers and professors from the orthopedic and rheumatologic and physiotherapy group and the Student Research Committee can apply for data.

Under which criteria data/document could be used

If data are used in studies and related articles by students of medical sciences, professors of orthopedic and rheumatologic and physiotherapy groups, etc., can be used.

From where data/document is obtainable

To the Center for Rheumatology Student Research Committee Mr. Hanzale Balakheili, Head of Rheumatology Student Research Committee in Sayad Shirazi Hospital. Phone:00989111789412 Dr. Afshin Sahebamei, Assistant Professor of Orthopedics, 5th Azar Hospital, Gorgan Phone: 00989155089335 Behfar Taziki, Medical Intern, Golestan University of Medical Science Phone:00989375435045

What processes are involved for a request to access data/document

After requesting from trial investigators, the Rheumatology Research Committee and the University's Ethics Committee, if approved, data are available.

Comments