Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The role of elbow exersices protocol in treatment of patients with lateral epycodylitis(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 pasive 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 exersices protocol in treatment of patients with lateral epycodylitis(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 Extention 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

Street address
Shahid Beheshti str

City
Gorgan

Province
Golestan

Postal code
4916655398

Phone
+98 17 3222 4848

Email
sahebjameiafshin@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Gorgan University of Medical Sciences

Full name of responsible person
Mohammad Reza Honarvar

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

City
Gorgan

Province
Golestan

Postal code
4918936316

Phone
+98 17 3245 1660

Email
info@goums.ac.ir

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
Medical Intern

Street address
Dezziani clinic of orthopaedi, Shahid Beheshti Str

City
Gorgan
Province
Golestan
Postal code
4916655398
Phone
+98 17 3222 4848
Email
Behfartaziki@goums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Afshin Sahebjamei
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Orthopedics
Street address
Dezziani clinic of orthopaedi, Shahid Beheshti Str
City
Gorgan
Province
Golestan
Postal code
4916655398
Phone
+98 17 3222 4848
Email
sahebjameiafshin@yahoo.com

Person responsible for updating data

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
Medical Intern
Street address
Dezziani clinic of orthopaedi, Shahid Beheshti Str
City
Gorgan
Province
Golestan
Postal code
4916655398
Phone
+98 17 3222 4848
Email
Behfartaziki@goums.ac.ir

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 Sahebjamei, 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