

# 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

###### **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

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4918936316

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+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**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Gorgan University of Medical Sciences  
**Full name of responsible person**  
Afshin Sahebamei  
**Position**  
Associate professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Orthopedics  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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A Level or less  
**Other areas of specialty/work**  
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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