

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparative evaluation of conservative treatment effects on humeral lateral epicondylitis

#### Protocol summary

##### Summary

Objectives: Comparative evaluation of using tennis elbow strap and physical therapy in conservative treatment of lateral humeral epicondylitis. Design: In this single blinded clinical trial 30 patients with lateral humeral epicondylitis will participate. Patients will be randomly assigned to one of the two treatment or control groups. The present study will be conducted in two patient recruiting centers at two phases with 2 weeks interval. Setting and conduct: The amount of pain, functional ability, grip force, pain threshold, and elbow range of motion will be evaluated by visual analog scale, PRTEE questionnaire, dynamometer, algometer, and goniometer, respectively. Two weeks after physical therapy or physical therapy with fastening tennis elbow strap, the amount of these variables will be evaluated again. Participants: Using judgmental non probability sampling method, those patients who met main inclusion criteria of age range between 35-50 years, lateral epicondyle pain history more than 6 weeks and lesser than 6 months, and no use of pain killer medications will be selected. Moreover, the main exclusion criteria are elbow joint movement limitation and bilateral lateral epicondylitis. Intervention: In intervention group tennis elbow strap will be used besides to physical therapy while in the control group just physical therapy will be used. Main outcome measures: Pain, functional ability, grip force, pain threshold, and elbow range of motion

#### General information

##### Acronym

-

##### IRCT registration information

IRCT registration number: **IRCT2015110224596N2**

Registration date: **2015-12-12, 1394/09/21**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2015-12-12, 1394/09/21

##### Registrant information

###### Name

Kamiar Ghoseiri

###### Name of organization / entity

Hamadan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 3838 1571

###### Email address

k.ghoseiri@umsha.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice Chancellor for Research of the Hamadan University of Medical Sciences

##### Expected recruitment start date

2016-01-21, 1394/11/01

##### Expected recruitment end date

2016-04-20, 1395/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparative evaluation of conservative treatment effects on humeral lateral epicondylitis

##### Public title

Treatment of Tennis Elbow

##### Purpose

Diagnostic

## Inclusion/Exclusion criteria

Inclusion Criteria: Age range from 35 - 50 years; Existence of tennis elbow and pain in lateral epicondyle of the humerus based on Moudsley and Mills tests during clinical examination by specialty physician; Existence of pain at lateral epicondyle for more than 6 weeks and less than 6 months; Signing the consent form to agree participating in study; No use of pain killer medications and Corticosteroid injection Exclusion Criteria: Limited elbow joint range of motion based on clinical examination; Bilateral tennis elbow; Neck and shoulder pain referrals; No ability to filling out questionnaires; Any fracture or history of surgery at arm and forearm; Any type of arthritis in upper extremities

### Age

From **35 years** old to **50 years** old

### Gender

Both

### Phase

1

### Groups that have been masked

*No information*

### Sample size

Target sample size: **30**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Single blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

Randomization will be done by selecting a paper piece that contain a type of treatment.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Hamadan University of Medical Sciences

##### Street address

Mahdiyeh Ave, In front of Mellat park

##### City

Hamadan

##### Postal code

##### Approval date

2015-10-31, 1394/08/09

##### Ethics committee reference number

IR.UMSHA.REC.1394.349

## Health conditions studied

### 1

#### Description of health condition studied

Lateral Epicondylitis

#### ICD-10 code

M77.1

#### ICD-10 code description

Lateral epicondylitis

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

Before intervention and 2 weeks after intervention

#### Method of measurement

Visual Analog Scale

### 2

#### Description

Function

#### Timepoint

Before intervention and 2 weeks after intervention

#### Method of measurement

PRTEE Questionnaire

### 3

#### Description

Grip Force

#### Timepoint

Before intervention and 2 weeks after intervention

#### Method of measurement

Jamar Dynamometer

### 4

#### Description

Pain Threshold of lateral Epicondyle

#### Timepoint

Before intervention and 2 weeks after intervention

#### Method of measurement

Algometer

### 5

#### Description

Elbow range of Motion

#### Timepoint

Before intervention and 2 weeks after intervention

#### Method of measurement

Electrical Goniometer

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: 14 sessions of physical therapy by manipulation, muscle stretching, muscle strengthening, and ultrasound with using prefabricated neoprene Tennis Elbow Strap for two weeks

#### Category

Treatment - Other

### 2

#### Description

Control group: 14 sessions of physical therapy by manipulation, muscle stretching, muscle strengthening, and ultrasound

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Besat Hospital

##### Full name of responsible person

Kamiar Ghoseiri

##### Street address

Shahid Beheshti Blvd, Besat Hospital

##### City

Hamadan

### 2

#### Recruitment center

##### Name of recruitment center

Shahid Mobasher Kashani Hospital

##### Full name of responsible person

Kamiar Ghoseiri

##### Street address

Mahdijeh Ave, Shahid Mobasher Kashani Hospital

##### City

Hamadan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for Research of the Hamadan University of Medical Sciences

##### Full name of responsible person

Dr. Bashirian

##### Street address

Mahdijeh Ave, In front of Mellat Park

##### City

Hamadan

#### Grant name

#### Grant code / Reference number

-

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Vice Chancellor for Research of the Hamadan University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

empty

#### Domestic or foreign origin

empty

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

empty

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Hamadan University of Medical Sciences

##### Full name of responsible person

Kamiar Ghoseiri

##### Position

Assistant Professor

##### Other areas of specialty/work

##### Street address

Mahdijeh Ave, In front of Mellat Park

##### City

Hamadan

##### Postal code

##### Phone

+98 81 3838 1571

##### Fax

##### Email

k.ghoseiri@umsha.ac.ir; kamiar\_g@yahoo.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Hamadan University of Medical Sciences

##### Full name of responsible person

Kamiar Ghoseiri

##### Position

Assistant Professor

##### Other areas of specialty/work

##### Street address

Mahdijeh Ave, In front of Mellat Park

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+98 81 3838 1571

##### Fax

**Email**

K.ghoseiri@umsha.ac.ir; kamiar\_g@yahoo.com

**Web page address****Fax****Email**

K.ghoseiri@umsha.ac.ir; kamiar\_g@yahoo.com

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Hamadan University of Medical Sciences

**Full name of responsible person**

Kamiar Ghoseiri

**Position**

Assistant Professor

**Other areas of specialty/work****Street address**

Mahdiyeh Ave, In front of Mellat Park

**City**

Hamadan

**Postal code****Phone**

+98 81383811571

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*