

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 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)

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+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

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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