Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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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
Mahdiyeh Ave, Shahid Mobasher Kashani Hospital
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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
Mahdiyeh 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
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Person responsible for updating data

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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