Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Efficacy Of Elbow Strap in The Treatment of Patients with Lateral Epicondylitis referring to Imam Khomeini Hospital

Protocol summary

Study aim

Main goal:The effect of elbow strap on the treatment of patients with Tennis Elbow referring to Imam Khomeini Clinic. Sub main: to compare the rate of pain relief in the sixth week after the treatment of Tennis Elbow in two groups of patients; to compare the rate of pain relief in the twelveth week after the treatment of Tennis Elbow in two groups of patients; to compare the function of the involved organ in the sixth week after the treatment of Tennis Elbow in two groups of patients; using the brace and without the brace; to compare the function of the involved organ in the twelveth week after the treatment of Tennis Elbow in two groups of patients. Functional goals: to obtain new information and use the results of research to treat Tennis Elbow with a non-invasive method.

Design

Randomized, single blind, parallel group clinical trial.

Settings and conduct

Patients with tennis elbow referring to the orthopedic clinic of Imam Khomeini Hospital will be treated after the initial recording of the data and evaluable variables, satisfaction, and randomization in the intervention group. Group1 receive Naproxen for 6 weeks and In group 2, in addition to Naproxen, they receive elbow strap for 12 weeks. Blinding is done for the clinical evaluator, but the physician and patients are well aware of the treatment. Patients 6 and 12 weeks after treatment, will re-evaluate and clinical findings will analyze.

Participants/Inclusion and exclusion criteria

All patients over the age of 20 who without existing of an anomaly, surgery, fracture in affected limb or not regularly using of elbow strap.

Intervention groups

1: patients under treatment with Naproxen; 2: patients under treatment with Naproxen and Elbow Sap

Main outcome variables

Pain, the function of the affected limb

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190213042708N1**
Registration date: **2019-03-20, 1397/12/29**
Registration timing: **registered_while_recruiting**

Last update: **2019-03-20, 1397/12/29**
Update count: **0**

Registration date

2019-03-20, 1397/12/29

Registrant information

Name

Seyede Sara Mehdinasab

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3336 4504

Email address

mn.sara94@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-09, 1397/12/18

Expected recruitment end date

2020-03-08, 1398/12/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Efficacy Of Elbow Strap in The Treatment of Patients with Lateral Epicondylitis referring to Imam Khomeini Hospital

Public title
The Efficacy Of Elbow Strap in The Treatment of Patients with Lateral Epicondylitis referring to Imam Khomeini Hospital

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All patients over the age of 20 years are referred to the orthopedic clinic of Ahvaz Imam Khomeini Hospital and have been diagnosed with Tennis elbow are included in the study. This diagnosis is based on physical examination, including pain in the lateral epicondyle, localized tenderness, and exacerbation of pain with the passive extension of the wrist and elbow supination against the resistance

Exclusion criteria:
Other anomalies and abnormalities in the hands, forearms, elbows and necks Surgery in the affected limb Previous history of fracture in the affected limb History of corticosteroid injection or other invasive methods in the past 3 months The history of rehabilitation and physiotherapy in the last 3 months The history of taking non-steroidal anti-inflammatory drugs or acetaminophen during the last week Not regularly using of elbow strap

Age
From **20 years** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **68**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are randomly divided into two groups based on randomized 4-way permutation.

Blinding (investigator's opinion)
Single blinded

Blinding description
The doctor and the patient are aware of the patient's treatment method, but those who measure the response to treatment variables do not have any information on the patient's treatment.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ahvaz Jondy Shapoor University of Medical Sciences

Street address
Ahvaz Jundishapur University of Medical Sciences and Health Services,. University of Medical Science,. Golestan Blvd.

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Approval date
2019-02-05, 1397/11/16

Ethics committee reference number
IR.AJUMS.REC. 1397 .835

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
to investigate the effect of elbow strap on lateral epicondylitis

Timepoint
0, 6, 12 weeks after starting treatment

Method of measurement
VAS Score

2

Description
Function of affected limb

Timepoint
0, 6, 12 weeks after starting treatment

Method of measurement
MEPS

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: Patients receive Naproxen 500 mg for 6 weeks and 3 times a day.
Category
Treatment - Drugs

2

Description
Intervention group 2: All patients in this group receive 500 mg of Naproxen and elbow strap treatment. Duration of drug administration is 6 weeks and 3 times a day, and elbow strap is for 12 weeks.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Orthopedic Clinic of Ahvaz Imam Khomeini Hospital
Full name of responsible person
Payam Mohammad hoseini
Street address
Ahvaz Imam Khomeini Hospital,. Azadegan Blvd.
City
Ahvaz
Province
Khouzestan
Postal code
6193673111
Phone
+98 61 3292 1836
Email
mohammadhoseini-p@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad Badavi
Street address
Student Research Committee,. Ahvaz Jundishapur University of Medical Sciences,. university town.
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3336 2414
Email
itc@ajums.ac.ir
Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Payam Mohammadhoseini
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Orthopedics
Street address
Orthopedic clinic of Imam Khomeini Hospital,. Azadegan Blvd,.
City
Ahvaz
Province
Khouzestan
Postal code
6193673111
Phone
+98 61 3292 1836
Email
mohammadhoseini-p@ajums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Payam Mohammadhoseini
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Orthopedics
Street address

Orthopedic clinic of Imam Khomeini Hospital,. Azadegan Blvd,.

City
Ahvaz

Province
Khouzestan

Postal code
6193673111

Phone
+98 61 3292 1836

Email
mohammadhoseini-p@ajums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Seyede Sara Mehdinasab

Position
Medical student

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

Street address
No. 33, East Mordad Ave,. Shahid Chamran Blvd,. Kianpars Town

City
Ahvaz

Province
Khouzestan

Postal code
6155693183

Phone
+98 61 3336 4504

Email
mn.sara94@gamil.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

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, the general information of patients such as age, gender, occupation, and part of data related to the outcome of the study can be shared after deleting the patient names.

When the data will become available and for how long
This result will be accessible after publishing the dissertation.

To whom data/document is available
All academic researchers can apply for information.

Under which criteria data/document could be used
The patients' documentation is only accessible to academic researchers in order to acquire knowledge with the observance of ethical principles and patients' privacy as well as without any changes in the study.

From where data/document is obtainable
All applicants can receive the required information by sending an E-mail to mn.sara94@gmail.com

What processes are involved for a request to access data/document
Applicants, please identify the reason for requesting the patients’ information.

Comments