

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

The immediate sensori-motor effects of elbow orthoses in people with lateral elbow tendinopathy: A randomized cross-over study

Protocol summary

Study aim

Assessing the immediate effect of two counter-force orthoses for improvement of sensori-motor abilities of the hand in patients with lateral elbow tendinopathy

Design

Cross-over Randomized controlled trial with 50 participants enrolled between Aug 2017 to Jan 2018.

Settings and conduct

This was a randomized controlled crossover study, during which participants acted as their own controls (no orthosis) and compare to two counterforce orthoses (including a forearm band and an elbow sleeve) in a single session. The order of intervention and testing conditions were randomized and determined by taking a concealed draw from a bag. The testing protocol was started after orthoses were fitted and 5 minutes acclimatization. Participants were given about 5 minutes rest and the crossed-over to the second orthosis. For all measurements, the test was explained and demonstrated to the participant.

Participants/Inclusion and exclusion criteria

Lateral elbow tendinopathy was diagnosed using three following criteria: 1) pain on palpation of the lateral epicondyle, 2) elbow pain aggravated with resisted wrist extension, and 3) pain on resistive middle finger extension. Participants tested positive in all three criteria were included. People with history of surgery, fracture, dislocation, or injection to the elbow less than 6 weeks prior were excluded.

Intervention groups

Two frequently used counterforce orthoses in lateral elbow tendinopathy were compared with "no orthosis" condition: forearm band and elbow sleeve .

Main outcome variables

Pain severity, elbow proprioception, hand grip strength, and finger dexterity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150210021034N1**

Registration date: **2018-05-17, 1397/02/27**

Registration timing: **retrospective**

Last update: **2018-05-17, 1397/02/27**

Update count: **0**

Registration date

2018-05-17, 1397/02/27

Registrant information

Name

Ebrahim Sadeghi-Demneh

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2017-11-21, 1396/08/30

Actual recruitment start date

2017-08-11, 1396/05/20

Actual recruitment end date

2018-01-20, 1396/10/30

Trial completion date

empty

Scientific title

The immediate sensori-motor effects of elbow orthoses in people with lateral elbow tendinopathy: A randomized cross-over study

Public title

The sensori-motor effects of elbow orthoses in tennis elbow

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Pain on palpation of the lateral epicondyle. Elbow pain aggravated with resisted wrist extension. Pain on resistive middle finger extension

Exclusion criteria:

People with history of surgery, fracture, dislocation, or injection to the elbow less than 6 weeks prior were excluded

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

The order of intervention and testing conditions were randomized and determined by taking a concealed draw from a bag.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethical committee of Isfahan University of Medical Sciences, Isfahan, Iran

Street address

Hezar Jerib St.

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Province

Isfahan

Postal code

8174673461

Approval date

2017-06-17, 1396/03/27

Ethics committee reference number

IR.MUI-REC-1396.3.216

Health conditions studied

1

Description of health condition studied

Tennis elbow

ICD-10 code

M77.1

ICD-10 code description

Lateral epicondylitis

Primary outcomes

1

Description

Pain

Timepoint

5 minutes after each intervention was applied.

Method of measurement

The pain severity was measured using a 10-cm visual analogue scale (VAS) in which 0 represented "no pain" and 10 indicated "the most severe pain" .

2

Description

Hand grip strength

Timepoint

5 minutes after each intervention was applied.

Method of measurement

Pain-free grip on the involved side was measured using a digital handgrip dynamometer (YDM-110, Yagami Ltd, Tokyo, Japan). Each participant stood with shoulder in neutral, elbow in extension and forearm in neutral position of supination/pronation then slowly squeeze the dynamometer handle until they felt pain at elbow

3

Description

Elbow joint position sense

Timepoint

5 minutes after each intervention was applied.

Method of measurement

Elbow proprioception was evaluated by the measurement of joint position sense. For this purpose, the ability of active angle reproduction was measured at the involved elbow. The participant sat on a chair and the arm is kept undisturbed and parallel to the floor using an adjustable arm support attached to the chair's handle. The participant's eyes were closed during proprioception testing. The examiner kept the forearm and started slowly moving the elbow from 90° toward

extension until elbow reached in 70° of flexion. The elbow was kept at 70° for 20 seconds and participant was asked to memorize this position. The elbow returned to 90° and participant was asked to reproduce the target angle (70° of flexion). The active angle reproduction test was also employed when elbow moving toward flexion direction. Participants were asked to move their elbow from 90° toward further flexion until reached target angle was set at 110° of flexion.

Secondary outcomes

1

Description

Finger dexterity

Timepoint

5 minutes after intervention was applied.

Method of measurement

The finger dexterity was evaluated using “nine-hole peg test”. The testing instrument consist of a wooden board with nine hole and a counterpart has a shallow round dish contained nine pegs. The hole-board was centered in front of participant and shallow dish was on the involved side. Participant took the pegs one by one and put them in the holes, as quickly as could. They then removed the pegs one by one and replaced them in the shallow round dish. The time was recorded using a stopwatch from the moment participant reach the first peg until the last peg was put back in the dish.

Intervention groups

1

Description

Intervention group: The forearm band was an 8-cm-wide neoprene band fitted 2.5 cm below the elbow. A double layered neoprene pad was incorporated in the forearm band to apply a direct pressure to the origin of the extensor muscles. The elbow strap had a 5-cm-wide non-elastic strap to adjust the pressure on the pad.

Category

Rehabilitation

2

Description

Intervention group: The elbow sleeve was a neoprene support circumferentially contained the arm approximately 15 cm above and below the elbow. The elbow sleeve was fitted on the arm using two 5-cm-wide non-elastic straps above and below the elbow. Both types of counterforce orthoses had a range of available sizes to accommodate different participants' sizes.

Category

Rehabilitation

3

Description

Control group: No orthosis

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital, Isfahan, Iran

Full name of responsible person

Abolghasem Zarezadeh

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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

396216

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

Yes

Title of funding source

Esfahan 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
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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The finding will be submitted for publication in a scientific journal.

When the data will become available and for how long

The finding will be submitted for publication in a scientific journal.

To whom data/document is available

The finding will be submitted for publication in a scientific journal.

Under which criteria data/document could be used

The finding will be submitted for publication in a scientific journal.

From where data/document is obtainable

The finding will be submitted for publication in a scientific journal.

What processes are involved for a request to access data/document

The finding will be submitted for publication in a scientific journal.

Comments

The finding will be submitted for publication in a scientific journal.