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)

Phone

+98 31 3792 5235

Email address

sadeghi@rehab.mui.ac.ir

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.

City
Isfahan

Province
Isfehan

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 90º toward

extension until elbow reached in 70º of flexion. The elbow was kept at 70º for 20 seconds and participant was asked to memorize this position. The elbow returned to 90º and participant was asked to reproduce the target angle (70º of flexion). The active angle reproduction test was also employed when elbow moving toward flexion direction. Participants were asked to move their elbow from 90º toward further flexion until reached target angle was set at 110º 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
Street address
Sofeh Blvd
City
Isfahan
Province
Isfehan
Postal code
8174675731
Phone
+98 31 3620 2020
Email
alzahra@mui.ac.ir
Web page address
http://alzahra.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mahdi Nematbakhsh
Street address
Hezar Jerib St.
City
Isfahan
Province
Isfehan
Postal code
۷۳۴۶۱-۸۱۷۴۶
Phone
+98 31 3668 5149
Email
research@mui.ac.ir
Web page address
http://research.mui.ac.ir/fa/%D9%85%D8%B9%D8%A7%D9%88%D9%86-%D9%BE%DA%98%D9%88%D9%87%D8%B4%DB%8C-%D9%88%D9%81%D9%86%D8%A7%D9%88%D8%B1%DB%8C
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
Esfahan University of Medical Sciences

Full name of responsible person
Ebrahim Sadeghi

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Rehabilitation management

Street address
Hezar jerib St

City
Isfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 31 3792 5053

Email
sadeghi@rehab.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfarayen University of Medical Sciences

Full name of responsible person
Ebrahim Sadeghi

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Rehabilitation management

Street address
Hezar Jerib St.

City
Isfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 31 3792 5053

Email
sadeghi@rehab.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Ebrahim Sadeghi-Demneh

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Rehabilitation management

Street address
Hezar Jerib

City
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Province
Isfehan

Postal code
8174673461

Phone
+98 31 3792 5053

Email
sadeghi@rehab.mui.ac.ir

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.