

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The immediate effects of the clasp elbow orthosis with a textured pad on the pain intensity, hand grip strength, hand function and elbow

Protocol summary

Study aim

The aim of the present study was to investigate the immediate effect of elbow splints with textured pads on improving the sense of depth, pain intensity, hand grip and hand function in people with external elbow epicondylitis.

Design

An exploratory clinical study, each participant receive four interventions in a random order.

Settings and conduct

Participants in a one-hour treatment session (in person) at the orthopedic office or Al-Zahra Hospital in Isfahan, all four modes of intervention include: 1) splint elbow clamps with tissue pad 2) elbow strap 3) orthosync 4) without orthosis in random order , Will receive. The order of the tests and orthoses at each stage is determined randomly by removing the sealed envelope from inside a bag.

Participants/Inclusion and exclusion criteria

Inclusion criteria: in this study include increasing pain in the outer part of the elbow when performing extension movements with resistance in the wrist and third finger, and participants should be able to consciously participate in this research project. Exclusion criteria: any abnormalities in the hands and elbows, a history of fractures, dislocations, and surgery on the elbow joint.

Intervention groups

Participants in a treatment session will randomly receive all four modes of study, including 1) orthoses, 2) elbow splints with a textured pad, 3) elbow straps, and 4) no orthoses.

Main outcome variables

pain intensity hand grip strength hand function Deep sense of the elbow

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220203053925N1**

Registration date: **2022-03-14, 1400/12/23**

Registration timing: **prospective**

Last update: **2022-03-14, 1400/12/23**

Update count: **0**

Registration date

2022-03-14, 1400/12/23

Registrant information

Name

Faezeh Babaee

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 84 3323 5877

Email address

faezeh_babaee@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2022-07-23, 1401/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The immediate effects of the clasp elbow orthosis with a textured pad on the pain intensity, hand grip strength, hand function and elbow

Public title

The immediate effects of the orthosis on the tennis elbow syndrome

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

the age range of 30 to 55 years The report of diffuse and increasing pain in the external epicondyle of the humerus with active wrist and third finger extension movement, supination, and strong hand grip Ability to give an informed consent and participation in the study

Exclusion criteria:

Any abnormality or deformity in the hands, forearms, shoulders and neck area A history of fractures, dislocations, surgery on the elbow joint A history of corticosteroid injection in the period of six months before the participation Having a cervical radiculopathy, pathology or an involvement of the peripheral nerves of the elbow joint

Age

From **30 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **48**

More than 1 sample in each individual

Number of samples in each individual: **4**

Participants in a one-hour therapy session (in person) will receive all four modes of intervention, including: 1) elbow splints with a tissue pad 2) elbow straps 3) orthoses 4) without orthoses in random order.

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

IR.MUI.NUREMA.REC

Street address

Hezar Jerib

City

Isfahan

Province

Isfahan

Postal code

۷۳۴۶۱-۸۱۷۴۶

Approval date

2022-01-29, 1400/11/09

Ethics committee reference number

IR.MUI.NUREMA.REC.1400.215

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 score on the visual analoge scale

Timepoint

At the beginning of the study and after wearing each orthosis

Method of measurement

visual analoge scale

2**Description**

The amount of angle recorded to measure the sense of depth by a digital goniometer

Timepoint

At the beginning of the study and after wearing each orthosis

Method of measurement

digital goniometer

3**Description**

Painless grip strength

Timepoint

At the beginning of the study and after wearing each orthosis

Method of measurement

Digital dynamometer

Secondary outcomes**1****Description**

recorded number for hand function with minnessotta manual test

Timepoint

5 minutes after intervention

Method of measurement

Hand function is assessed using the Minnesota manual test.

Intervention groups

1

Description

Intervention group: the clasp elbow splint is made with house-shoe rigid thermoplastic material which covers two-third of forearm circumferential at the dorsal surface. This splint is fitted on the forearm using a velcro strap. The inner surface of the splint is covered with a soft foam material. At the lateral aspect of the splint, a textured silicon pad with semicircular projections is placed to provide skin stimulation at the lesion site.

Category

Rehabilitation

2

Description

Intervention group: elbow strap is 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

3

Description

Intervention group: placebo orthosis which is an 5 cm wide elastic neoprene band and is fitted 10 cm above the elbow using a velcro strap. Fitting the strap above the elbow is to prevent any effect that this splint might have on the lesion.

Category

Rehabilitation

4

Description

Control group: No orthosis, without wearing any splint

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Emerald building

Full name of responsible person

dr abolghasem zarezadeh

Street address

Shamsabadi Ave, Emerald building

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

dr mansour siavash dastjerdi

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Grant name

Grant code / Reference number

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

dr Ebrahim sadeghi demneh

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Rehabilitation management

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The study data (excluding the personal details) can be shared with other researchers or systematic reviewers.

When the data will become available and for how long

Data will be shared once findings are come up or summary date is published.

To whom data/document is available

Data will be shared once findings are come up or summary date is published.

Under which criteria data/document could be used

Data will be shared personally and for academic purposes only.

From where data/document is obtainable

Data will be shared for teaching or research. Dr Sadeghi (correspondence) will review the requests.

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

People can sent their request to the correspondence and obtain the data.

Comments

Request should be sent through an email (sadeghi@rehab.mui.ac.ir).