

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 hourse-shoe rigid thermoplastic material which covers two-third of forearm circumferential at the dorsal surface. This splint is fitted on the forarm using a velcro strp. 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 semicirculare 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 cmwide elastic neoperene 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

#### **City**

esfahan

#### **Province**

Isfahan

#### **Postal code**

8174675731

#### **Phone**

+98 31 3223 8750

#### **Email**

faezeh\_babae@yahoo.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Esfahan University of Medical Sciences

##### **Full name of responsible person**

dr mansour siavash dastjerdi

##### **Street address**

hazar jerib Ave

##### **City**

esfahan

##### **Province**

Isfahan

##### **Postal code**

7346181746

##### **Phone**

+98 31 3668 0048

##### **Email**

research@mui.ac.ir

#### **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

**Street address**

Hezar jerib Ave

**City**

esfahan

**Province**

Isfahan

**Postal code**

7346181746

**Phone**

+98 31 3792 5219

**Email**

sadeghi@rehab.mui.ac.ir

**Person responsible for scientific inquiries****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

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**Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

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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).