Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)
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+98 84 3323 5877
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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
Isfehan
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 elastice 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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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Person responsible for scientific inquiries

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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).