Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Design and construction of Dorsal forearm- wrist splint and compare with Dorsal Wrist cock-up splint and theirs effects on pain and grip force and function in patients with tennis elbow

Protocol summary

Study aim
Design and construction of Dorsal forearm- wrist splint and compare with Dorsal Wrist cock-up splint and theirs effects on pain and grip force and function in patients with tennis elbow

Design
This prospective study is a randomized clinical trial with parallel groups.

Settings and conduct
Sampling will be done in a simple and accessible way among the people who have the conditions to enter our study who have referred to the technical orthopedic clinics in Isfahan and the orthopedic specialist.

Participants/Inclusion and exclusion criteria
Pain rate, grip strength, function by VAS test, dynamometer, (Nine hole peg test) on patients with eligible patients who have referred to technical orthopedic clinics in Isfahan and orthopedic physicians, respectively. it is going to happen. The study will be performed on 28 people, which has been calculated according to a similar study in G-Power software. They will be divided into two groups of 14 people, each group will use an orthosis and will be evaluated before and after 4 weeks of follow-up. Inclusion criteria for the present study: 1. Includes being in the age range of 30 to 55 years. 2. Report of chronic pain in the external epicondyle of the humerus 3. Ability to respond and participate consciously in research Exclusion criteria: 1. Existence of any disorders and abnormalities in the hands, forearms, shoulders and neck area of people 2. History of fracture, dislocation, surgery on the elbow joint 3. History of corticosteroid injection (corticosteroids) in the period of six months before the study

Intervention groups
Subjects with tennis elbow syndrome separate into two groups. The control group used a short dorsal splint and the intervention group used a dorsal-forearm splint.

Main outcome variables
pain - grip force - function

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200516047459N4**
Registration date: **2021-06-23, 1400/04/02**
Registration timing: **registered_while_recruiting**

Last update: **2021-06-23, 1400/04/02**
Update count: **0**

Registration date
2021-06-23, 1400/04/02

Registrant information
Name
Masoud Rafiaei
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 31 3792 5043
Email address
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-06-22, 1400/04/01
Expected recruitment end date
2021-09-22, 1400/06/31
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Design and construction of Dorsal forearm- wrist splint and compare with Dorsal Wrist cock-up splint and theirs effects on pain and grip force and function in patients with tennis elbow

Public title

effect of wrist hand orthosis on subjects with tennis elbow

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age between 30 to 55 years Report of chronic pain in the lateral epicondyle of the humerus, which increases with active movement of the wrist and third finger, supination, and strong force in the hand, and indicates the presence of dissatisfaction or tennis elbow, which should be mild to moderate symptoms (vas≥3). Ability to respond and participate consciously in research

Exclusion criteria:

1. Existence of any disorders and abnormalities in the hands, forearms, shoulders and neck area 2. History of fracture, dislocation, surgery on the elbow joint 3. History of corticosteroid injection in the period of six months before the study.

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: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

Subjects are randomly divided into 2 groups. The order of the tests at each stage is determined randomly by removing the closed pocket. In this way, orthoses are held between the two main groups, which are dorsal wrist - forearm orthosis and cock up and one of these two orthoses is delivered to the first person and the second to the second person and evaluated, and thus subjects will be divided into two groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of medial university of isfahan

Street address

Hezarjerib

City

Isfahan

Province

Isfehan

Postal code

81746-73461

Approval date

2021-05-08, 1400/02/18

Ethics committee reference number

IR.MUI.NUREMA.REC.1400.014

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

4 weeks

Method of measurement

visual analogue scale

Secondary outcomes

1

Description

grip force

Timepoint

4 weeks

Method of measurement

dynamometer

Intervention groups

1

Description
The control group includes subjects who use cock-up orthosis which cover the palmar surface of the hand and wrist area and cause stability in this area. This orthosis is made of polyethylene and its use time is 4 weeks. Subjects will be taught how to use the orthosis correctly by the researcher.

Category
Rehabilitation

2

Description
The intervention group includes subjects using dorsal wrist forearm orthoses which cover the dorsal surface of the hand, forearm and wrist area and cause stability in this area. This orthosis is made of polyethylene and its use time is 4 weeks. Subjects will be taught how to use the orthosis correctly by the researcher.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra hospital, Isfahan

Full name of responsible person
Masoud Rafiaei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research and Technology, Isfahan University of Medical Sciences

Full name of responsible person
shaghayegh Haghjooyejavanmard

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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
Vice Chancellor for Research and Technology, Isfahan 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
Masoud Rafiaei

Position
Assistant Professor

Latest degree
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Other areas of specialty/work
Orthopedics

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Person responsible for updating data

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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
data will be published from university.
When the data will become available and for how long
one year
To whom data/document is available
researchers
Under which criteria data/document could be used
future research
From where data/document is obtainable
The main performer
What processes are involved for a request to access data/document
e-mail
Comments