

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The immediate effects of two splinting methods on pain and hand function in people with triangular fibrocartilage complex injury: a randomized crossover study

Protocol summary

Study aim

The objective of this study is to compare the effectiveness of two types of splints, including short cock-up as commonly used static orthosis for the lesion and a newly-design splint (hinged ulnar gutter) on wrist pain and hand function in people with degenerative lesions of triangular fibrocartilage complex.

Design

This is a crossover clinical trial. The sample size was determined based on the previous similar studies and set at 20 participants. All participants were put in a single group and received interventions in a random order. Randomization of intervention was determined by drawing a concealed envelop from a bag.

Settings and conduct

Participants will be recruited from outpatient clinic in Alzahra hospital, Isfahan, Iran through a convenience sampling method.

Participants/Inclusion and exclusion criteria

Inclusion Criterion of the study includes the presence of a damage to triangular fibrocartilage complex of the wrist. Exclusion Criteria of the study include taking nonsteroidal anti-inflammatory drugs, a history of corticosteroid injections, history of fractures in the forearm and wrist and receiving any concurrent treatment for the lesion.

Intervention groups

In this study, four conditions are allocated to each participants which include the use of a short cock-up, the use of a new wrist splint (hinged ulnar gutter) as the study interventions, and the use of a wristband (placebo) and without a splint as control groups.

Main outcome variables

Pain severity, hand function, grip strength, wrist weight bearing tolerance, and range of motion for the wrist and forearm complex.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150210021034N9**

Registration date: **2020-06-22, 1399/04/02**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-22, 1399/04/02**

Update count: **0**

Registration date

2020-06-22, 1399/04/02

Registrant information

Name

Ebrahim Sadeghi-Demneh

Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2020-07-19, 1399/04/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The immediate effects of two splinting methods on pain and hand function in people with triangular fibrocartilage complex injury: a randomized crossover study

Public title

The immediate effects of two hand splints in people with triangular fibrocartilage complex injury

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Positive ulnocarpal stress sign Ulnar side wrist pain because of ulnocarpal abutment syndrome

Exclusion criteria:

Taking NSAIDs medications Corticosteroid injection History of wrist and forearm fracture Receiving concurrent treatments for the lesion

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 20

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

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 street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2019-02-27, 1397/12/08

Ethics committee reference number

IR.MUI.RESEARCH.REC.1397.475

Health conditions studied

1

Description of health condition studied

degenerative injury of triangular fibrocartilage complex

ICD-10 code

S64

ICD-10 code description

Injury of nerves at wrist and hand level

Primary outcomes

1

Description

Pain severity

Timepoint

All interventions will be allocated in a session and outcomes will be measured 10 minutes after receiving interventions.

Method of measurement

Pain intensity will be measured using visual analogue scale. Participants indicate their pain level on a 10 cm scale.

2

Description

range of motions at the wrist

Timepoint

All interventions will be done in a session and outcomes will be measured 10 minutes after receiving interventions.

Method of measurement

The passive range of motion will be measured using a digital goniometer.

3

Description

The wrist weight bearing tolerance

Timepoint

All interventions will be allocated in a session and outcomes will be measured 10 minutes after receiving trial interventions.

Method of measurement

Participants push on a weight recording scale with the palmar surface of the hand.

4

Description

Hand grip strength

Timepoint

All interventions will be allocated in a session and outcomes will be measured 10 minutes after receiving

trial interventions.

Method of measurement

Hand grip on the involved side will be measured using a digital handgrip dynamometer.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The short cockup splint made from thermoplastic sheet. This rigid splint covers the volar surface of the hand from the proximal palmar crease to two-third of forearm area. Thumb freely moves in this splint. This splint is custom made for each participant. Each participant will be given about ten minutes to be accommodated with device then measurements will be carried out while device is worn.

Category

Treatment - Devices

2

Description

Intervention group: The hinged ulnar gutter splint consists of two thermoplastic bars placed on the hand and forearm area. This splint fits over ulnar side of the hand and prevents the ulnar deviation of the wrist. The sagittal motions of the wrist and thumb movements are not restricted. This splint is custom made for each participant. Each participant will be given about ten minutes to be accommodated with device then measurements will be carried out while device is worn.

Category

Treatment - Devices

3

Description

Control group: The elastic wrist support which covers the middle area of the forearm to palmar surface of the hand and does not apply any mechanical restriction for motions in the hand and forearm. This splint is custom fitted for each participant. Each participant will be given about ten minutes to be accommodated with device then measurements will be carried out while device is worn.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital, Isfahan, Iran

Full name of responsible person

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

Mahdi Nematbakhsh

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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
Ebrahim Sadeghi-Demneh
Position
Associate professor
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Person responsible for scientific inquiries

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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

Not applicable

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

No specific limitation is considered.

To whom data/document is available

No specific limitation is considered.

Under which criteria data/document could be used

No terms and conditions is considered for sharing the data.

From where data/document is obtainable

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

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

Request should be sent through an email.

Comments