

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3792 5235

##### Email address

sadeghi@rehab.mui.ac.ir

##### 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

##### **Street address**

Sofeh Blvd

##### **City**

Isfahan

##### **Province**

Isfahan

##### **Postal code**

8174675731

##### **Phone**

+98 31 3620 2020

##### **Email**

alzahra@mui.ac.ir

##### **Web page address**

<http://alzahra.mui.ac.ir>

### **Sponsors / Funding sources**

#### **1**

##### **Sponsor**

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

Esfahan University of Medical Sciences

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

Mahdi Nematbakhsh

###### **Street address**

Hezar Jerib St.

###### **City**

Isfahan

###### **Province**

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###### **Postal code**

۷۳۴۶۱-۸۱۷۴۶

###### **Phone**

+98 31 3668 5149

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research@mui.ac.ir

###### **Web page address**

<http://research.mui.ac.ir/fa/%D9%85%D8%B9%D8%A7%D9%88%D9%86-%D9%BE%DA%98%D9%88%D9%87%D8%B4%DB%8C-%D9%88%D9%81%D9%86%D8%A7%D9%88%D8%B1%DB%8C>

##### **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

**Latest degree**  
Ph.D.

**Other areas of specialty/work**  
Rehabilitation management

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## Person responsible for scientific inquiries

### Contact

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Esfahan University of Medical Sciences

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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