

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The comparison of the immediate effects of two types of Thumb splint on pain, grip strength and hand function of people with de quervain's disease: a randomised crossover study

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

The aim of this study was to compare the effect of two types of Palmar abduction and radial abduction splints On pain, hand function and hand grip in people with dequervain disease

Last update: **2020-10-06, 1399/07/15**

Update count: **0**

Registration date

2020-10-06, 1399/07/15

Design

This is a crossover clinical trial. The sample size was determined based on the previous similar studies and set at 30 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.

Registrant information

Name

Hanieh Mohammadzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Settings and conduct

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

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

The inclusion criteria for people with dequervain disease with pain in the radial said of the wrist and positive Finkelstein test and the average pain in the acute phase is 3 . the exclusion criteria for people with arthritis and those who have undergone surgery or injection in the last 6 months to treat the disease

Expected recruitment start date

2019-07-05, 1398/04/14

Expected recruitment end date

2020-12-19, 1399/09/29

Intervention groups

In this study, for each person, three conditions are allocated to each participants without splint, with Palmar abduction splint and with radial abduction splint

Actual recruitment start date

empty

Actual recruitment end date

empty

Main outcome variables

Pain, Hand function and hand grip strength

Trial completion date

empty

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190925044885N1**

Registration date: **2020-10-06, 1399/07/15**

Scientific title

The comparison of the immediate effects of two types of Thumb splint on pain, grip strength and hand function of people with de quervain's disease: a randomised crossover study

Public title

Effects of splint on dequervain's disease

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Positive result of finkelstine Pain on radial said of wrist
 Average of pain should be 3 and people should be in acute situation
Exclusion criteria:
 People with osteoarthritis and different arthritis
 Corticosteroid injection and surgery

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 30

Randomization (investigator's opinion)
Randomized

Randomization description
The order of intervention and testing conditions were randomized and determined by taking a concealed draw from a bag

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics committee of Esfahan University of Medical Sciences
Street address
 Hezarjarib
City
 Esfahan
Province
 Isfahan
Postal code
 8174673461
Approval date
 2019-02-06, 1397/11/17
Ethics committee reference number
 IR.MUI.RESEARCH.REC.1397.379

Health conditions studied

1

Description of health condition studied

De Quervain Disease

ICD-10 code

M65.4

ICD-10 code description

Radial styloid tenosynovitis [de Quervain]

Primary outcomes

1

Description

Intensity of pain

Timepoint

All interventions are given to the participant in one session and result of the study situations result are record after 20 minutes.

Method of measurement

Pain intensity is measured with a visual pain scale. People show their pain intensity on a 10 cm ruler.

2

Description

Strength of the hand grip

Timepoint

All interventions are given to the participant in one session and result of the study situations result are record after 20 minutes.

Method of measurement

The power of holding objects in the hand is measured by a hand-held dynamometer

3

Description

Hand function

Timepoint

All interventions are given to the participant in one session and result of the study situations result are record after 20 minutes.

Method of measurement

Hand function measure with Jebson Taylor test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Palmar abduction splint, thumb is abducted from the palm of the hand and covers the end of the metacarpal of the fingers, the end of the thumb is free and extends up to two thirds of the forearm, which is made of thermoplastic and custom-made for people. To

each participant about ten minutes is given to get used to the device then Measurements are made while the device is covered.

Category

Treatment - Devices

2**Description**

Intervention group: Radial abduction splint, thumb is abducted from the fingers and covers the end of the metacarpal of the fingers, the end of the thumb is free and extends up to two thirds of the forearm, which is made of thermoplastic and is custom made for people. Each participant about ten minutes is given to get used to the device then Measurements are made while the device is covered.

Category

Treatment - Devices

Recruitment centers**1****Recruitment center****Name of recruitment center**

Alzahra hospital

Full name of responsible person

Abolghasem Zarezadeh

Street address

Alzahra hospital, Hezarjarib street

City

Esfahan

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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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Hezarjarib street

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Isfahan

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research@mui.ac.ir

Web page address

https://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

Ebrahim Sadeghi-Demne

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Rehabilitation management

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

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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

Study information (other than personal information) with other researchers Will be shared

When the data will become available and for how long

There are no specific restrictions

To whom data/document is available

There are no specific restrictions

Under which criteria data/document could be used

No condition is specified

From where data/document is obtainable

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

Esfahan University of Medical Sciences

Full name of responsible person

Ebrahim Sadeghi-Demneh

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