Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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

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.

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
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

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

Main outcome variables
Pain,Hand function and hand grip strength

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190925044885N1**
Registration date: **2020-10-06, 1399/07/15**
Registration timing: **registered_while_recruiting**

Last update: **2020-10-06, 1399/07/15**
Update count: **0**

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

Registrant information
Name
Hanieh Mohammadzadeh
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 2671 3572
Email address
haniehmohammadzadeh927@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-05, 1398/04/14

Expected recruitment end date
2020-12-19, 1399/09/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

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

Isfehan

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

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8174675731

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r.ac.mui@a

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

Hezajarib street

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Province

Isfehan

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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

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Position

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Person responsible for updating data

Contact
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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