

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Investigating the therapeutic effect of thumb spica cast after De quervain's disease injection on the recovery rate of patients

Protocol summary

Study aim

Determination of the therapeutic effect of taking spike thumb plaster after injection of decron's disease in the rate of recovery of patients by age Determination of the therapeutic effect of taking spike thumb plaster after injection of decron's disease in the rate of recovery of patients by gender Determination of the therapeutic effect of taking spike thumb plaster after injection of decron's disease in the recovery rate of patients based on underlying disease Determination of the therapeutic effect of taking spike thumb plaster after injection of decron's disease in the recovery rate of patients based on smoking

Design

Clinical trial with control group.randomized, on 60 patients of the intervention group and 82 patients of the control group. Rand function is used to randomize Excel software.

Settings and conduct

Clinical trial,bowali hospital in tehran We examine the De quervain's patients who visit the boweli hospital, some of whom we treat only with topical injection therapy methyl prednisolone, and some of whom we take thumb spica cast in addition to the injection,, two to three weeks later we open the cast and check the abilities of the two groups based on two Vas and DASH questionnaires.

Participants/Inclusion and exclusion criteria

Entry requirements: visit to the Bowali hospital Consent to participate in the study Conditions for non-entry: incomplete patient information Lack of access to the patient to follow up on the outcome of the treatment

Intervention groups

Intervention group: taking spyca thumb plaster after injection treatment methyl prednisolone acetate (1 cc) with 1 cc lidocaine 2% Control group: injectable treatment of methyl prednisolone acetate (1 cc) with 1 cc of lidocaine 2%

Main outcome variables

Improvement of symptoms and pain of the patient's

thumb

General information

Reason for update

Acronym

گج اسپایکا، شست، بیماری دکرون

IRCT registration information

IRCT registration number: **IRCT20240122060766N1**

Registration date: **2024-02-16, 1402/11/27**

Registration timing: **registered_while_recruiting**

Last update: **2024-02-16, 1402/11/27**

Update count: **0**

Registration date

2024-02-16, 1402/11/27

Registrant information

Name

Suede hanieh Mohseni moghaddam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2612 7209

Email address

mohseni.hanieh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-23, 1402/11/03

Expected recruitment end date

2024-02-17, 1402/11/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the therapeutic effect of thumb spica cast after De quervain's disease injection on the recovery rate of patients

Public title

Investigating the therapeutic effect of thumb spica cast after De quervain's disease injection on the recovery rate of patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Consent to participate in the study Visit to the Bowali hospital

Exclusion criteria:

Incomplete patient information Lack of access to the patient to follow up on the outcome of the treatment

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **142**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly assigned to the study so that the patient and the doctor both do not know about the selected treatment group

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients with dequervain disease visiting the Bowali hospital in Tehran who are eligible to enter the study will be randomly selected and randomly divided into two groups of witnesses and interventions, so that the patient and the researcher will not know about the treatment received to relieve the symptoms of the thumb.

Placebo

Used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of the Islamic Azad University of Tehran Medical Sciences Unit

Street address

Zargande at,shariati at,tehran

City

Tehran

Province

Tehran

Postal code

1936893813

Approval date

2022-09-27, 1401/07/05

Ethics committee reference number

IR.IAU.TMU.REC.1401.215

Health conditions studied**1****Description of health condition studied**

De quervain disease

ICD-10 code

M67.8

ICD-10 code description

Other specified disorders of synovium and tendon

Primary outcomes**1****Description**

Improved wrist and thumb pain in de quervain's patients

Timepoint

One month

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: intervention group: thumb spica plaster after injection treatment methyl prednisolone acetate (1 cc) with 1 cc lidocaine 2%

Category

Treatment - Devices

2**Description**

Control group:injectable treatment of methyl prednisolone acetate (1 cc) with 1 cc of lidocaine 2%

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Bowali Hospital

Full name of responsible person

Dr Saeed Pezeshki

Street address

Bowali Hospital,Damavand A Imam Ali Exp,Tehran

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Tehran

Province

Tehran

Postal code

1711734365

Phone

+98 21 3334 8036

Email

booali.hospital96@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Ms Shahab pour

Street address

Zargande AVE,shariati street,tehran

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1949635881

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+98 21 2660 2642

Email

Int.affairs@tms.iau.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Islamic Azad University

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

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Seyede Hanieh Mohseni Moghadam

Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Saeed Pezeshki

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

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booali.hospital96@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

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Position

Medical student

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Fax**Email**

Mohseni.hanieh@yahoo.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable