

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation of the Effect of autologous blood transfusion on the treatment of De Quervain's tenosynovitis

Protocol summary

Summary

Objectives: Tenosynovitis of the first extensor compartment is known as De Quervain's disease. While transfusion of autologous blood has been widely used in the treatment of tendinopathy and considerable effect of this treatment has been reported in some investigations, no study has evaluated the effect of autologous blood transfusion on De Quervain's disease. In this study we aim to evaluate the therapeutic effect of autologous blood transfusion on De Quervain's disease. Design: Randomized controlled clinical trial Setting and conduct: A total number of 30 patients with confirmed diagnosis of De Quervain's disease made by a hand surgeon will be equally divided into intervention and control group. Inclusion criteria: Diagnosis of De Quervain's disease; age of 18 to 60 years; no history of rheumatic disorder such as rheumatoid arthritis; no history of depression and other mental disorders; no history of previous intervention for the treatment of De Quervain's disease. Exclusion criteria: loss of follow-up. Main outcome measures: Pain and disability level of the disease will be evaluated using visual analog scale and Persian version of Disabilities of the Arm, Shoulder and Hand (DASH) score once before the start of intervention and once 6 weeks after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017081635382N4**
Registration date: **2017-08-16, 1396/05/25**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-08-16, 1396/05/25

Registrant information

Name

Farid Najd Mazhar

Name of organization / entity

Shafa orthopedic hospital, Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 3354 2000

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor For research of Iran University of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effect of autologous blood transfusion on the treatment of De Quervain's tenosynovitis

Public title

Effect of autologous blood transfusion on the treatment of De Quervain's disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Diagnosis of De Quervain's disease; age of 18 to 60 years; no history of rheumatic disorder

such as rheumatoid arthritis; no history of depression and other mental disorders; no history of previous intervention for the treatment of De Quervain's disease. Exclusion criteria: loss of follow-up.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciences

Street address

Next to Milad tower, Hammat Highway

City

Tehran

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

-

Health conditions studied

1

Description of health condition studied

De Quervain's

ICD-10 code

M65.4

ICD-10 code description

Spontaneous rupture of synovium and tendon

Primary outcomes

1

Description

Pain

Timepoint

Before the start of the intervention and after the end of the intervention

Method of measurement

visual analog scale

2

Description

Disability

Timepoint

Before the start of the intervention and after the end of the intervention

Method of measurement

Disabilities of the Arm, Shoulder and Hand (DASH) score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group of patients 1 CC autologous blood of the patient will be transfused at the site of affected tendon.

Category

Treatment - Other

2

Description

Control group: In this group of patients placebo (normal saline) will be injected instead of autologous blood transfusion.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa Orthopedic Hospital

Full name of responsible person

Farid Najd Mazhar

Street address

Shafa Orthopedic Hospital, Mojahedin Islam Avenue, Shohada Square

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Iran University of Medical Sciences

Full name of responsible person

Morteza Naserbakht

Street address

Next to Milad tower, Hemmat Highway.

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for research of Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Shafa Orthopedic Hospital

Full name of responsible person

Farid Najd Mazhar

Position

Orthopedic surgeon/Science committee

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty