

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Evaluation of the results of deep flexor tendon healing of Zone II hand using 4-strand and 6-strand with prolene sutures

Protocol summary

Study aim

investigation of the results of deep flexor tendon healing of Zone II hand using 4-strand and 6-strand with prolene sutures

Design

This study is a non-blinded clinical trial. The study population will be included all patients with a ruptured deep flexor tendon of Zone II hand referred to Taleghani Hospital of Kermanshah. 50 eligible patients will be selected conveniently and randomly assigned to two intervention groups.

Settings and conduct

This study that will be conducted in Taleghani hospital of Kermanshah is a non-blinded one. Eligible patients will receive 4 and 6 strand suture tendon repair. Three months after the end of the study, the rate of remission will be compared in both groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with ruptured deep flexor tendons of the fingers Exclusion criteria: Patients with bone damage and crushing; Patients with a severe finger injury

Intervention groups

The first intervention group will receive a 4-strand suture tendon repair The second intervention group will receive a 6-strand suture tendon repair

Main outcome variables

Rate of remission

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N139**

Registration date: **2020-02-14, 1398/11/25**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-14, 1398/11/25**

Update count: **0**

Registration date

2020-02-14, 1398/11/25

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-14, 1398/11/25

Expected recruitment end date

2020-08-15, 1399/05/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the results of deep flexor tendon healing of Zone II hand using 4-strand and 6-strand with prolene sutures

Public title

Evaluation of the results of deep flexor tendon healing of Zone II hand using 4-strand and 6-strand with prolene sutures

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with ruptured deep flexor tendons of the fingers

Exclusion criteria:
Patients with bone damage and crushing Patients with severe finger injury

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Using the random number table, patients are divided into two groups of 25. Each patient is assigned a 4-digit code based on the random number table, Based on the right number of patients code, the patients are divided into two groups. Patients whose last digit is 0, 2, 4, 6, 8 will be assigned to the intervention group and patients whose last digit is 1,3,5, 7, 9 will be assigned to the control group.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2019-12-17, 1398/09/26

Ethics committee reference number

IR.KUMS.REC.1398.942

Health conditions studied

1

Description of health condition studied

Tendon repair

ICD-10 code

M66.3

ICD-10 code description

Spontaneous rupture of flexor tendons

Primary outcomes

1

Description

Rate of remission

Timepoint

3 months after the end of the study

Method of measurement

By the angle gauge

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group will receive a 4-strand suture tendon repair

Category

Treatment - Surgery

2

Description

The second intervention group will receive a 6-strand suture tendon repair

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Yosef Poorhesam

Street address

Shahid Beheshti Boulevard, Taleghani Hospital

City

Kermanshah

Province

Kermanshah

Postal code

6715847167

Phone

+98 83 3836 7984

Email

Y.poorhsam2020@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3836 0014

Email

fnajafi@kums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Yosef Poorhesam

Position

Resident of General Surgery

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

Street address

Shahid Beheshti Boulevard, Taleghani Hospital

City

Kermanshah

Province

Kermanshah

Postal code

6715847167

Phone

+98 83 3836 7984

Email

Y.poorhsam2020@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Mohammadbagher Heydari

Position

Member of Kermanshah University of Medical Sciences

Latest degree

Subspecialist

Other areas of specialty/work

Plastic Surgery

Street address

Emam Reza Hospital, Parastar Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3427 6306

Email

Mohammadbagher_heydari@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Yosef Poorhesam

Position

Resident of General Surgery

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

Street address

Shahid Beheshti Boulevard, Taleghani Hospital

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Province

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Email

Y.poorhsam2020@gmail.com

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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is 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

Title and more details about the data/document

The main outcomes of the study will be shared.

When the data will become available and for how long

6 months

To whom data/document is available

If requested, results will be made available to other academic researchers

Under which criteria data/document could be used

Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable

To receive the documentation, email send for update manager

What processes are involved for a request to access data/document

In a 15-day period, the documents will be sent e-mail

Comments