

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the outcomes of tendon transfer and tendon graft in delayed repair of flexor pollicis longus (FPL) tendon in Hazrat Fatemeh hospital in 2022

Protocol summary

Study aim

Comparison of the results of delayed repair of flexor pollicis longus (FPL) tendon with tendon transfer or with tendon graft in Hazrat Fatemeh hospital

Design

A randomized clinical trial with two parallel groups, 20 patients; randomization will be done by sealed pockets.

Settings and conduct

Patients who come to Hazrat Fatemeh Hospital with FPL tendon injury and it is possible that primary tendon repair is not possible in them, undergo surgery after obtaining consent. During surgery, if it is confirmed that primary repair is not possible, they are randomly placed in one of the two groups of tendon transfer or tendon graft and are operated with the specified method. After the operation, the usual care including splint for four weeks and physiotherapy will be done as necessary. At intervals of three and six months after the surgery, the range of motion of the IP and MP joints of the finger is determined and compared in two groups. Blinding of the surgeon is not possible, but the personnel of the occupational therapy unit who performs the measurements will be blinded to the surgical procedure.

Participants/Inclusion and exclusion criteria

Inclusion criteria: all of the patients with FPL tendon injury in whom primary repair of tendon is not possible. Exclusion criteria: the tendon injury is mild and do not need repair; primary repair of tendon is possible; patients who need hunter or pulley reconstruction; patients who prefer a specific method of tendon repair; patients who have limmited motion of thumb joints due to joint injury.

Intervention groups

One group will be repaired with tendon transfer and the other group with tendon graft.

Main outcome variables

Range of motion (ROM) of IP and MP joints of thumb in

the two groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211007052691N1**

Registration date: **2022-10-21, 1401/07/29**

Registration timing: **registered_while_recruiting**

Last update: **2022-10-21, 1401/07/29**

Update count: **0**

Registration date

2022-10-21, 1401/07/29

Registrant information

Name

Mehdi Tassalibakhsh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8871 7272

Email address

dr_tasallibakhsh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-07, 1401/07/15

Expected recruitment end date

2023-01-21, 1401/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the outcomes of tendon transfer and tendon graft in delayed repair of flexor pollicis longus (FPL) tendon in Hazrat Fatemeh hospital in 2022

Public title

Comparison of the results of delayed repair of flexor pollicis longus (FPL) tendon with tendon transfer or with tendon graft

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

patients with FPL tendon injury primary repair of tendon is not possible

Exclusion criteria:

patients prefer a specific method the tendon injury is mild and do not need repair patients who need hunter or pulley reconstruction due to injury to tendon tract patients who have limited joint motion due to joint injury

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 20

Randomization (investigator's opinion)

Randomized

Randomization description

we will have a simple randomization by sealed pockets. in each pocket one of the two methods of repair is written and for each patient one of the pockets will be opened.

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 Iran University of Medical Sciences

Street address

Room No. 346, 2th floor, medicine faculty, Iran University of Medical Sciences, beside of Milad Tower, Shahid Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2022-02-26, 1400/12/07

Ethics committee reference number

IR.IUMS.FMD.REC.1400.650

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

Flexor Pollicis longus tendon injury

ICD-10 code

T14.6

ICD-10 code description

Injury of muscles and tendons of unspecified body region

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

Range Of Motion of IP joint of the injured thumb

Timepoint

3 and 6 months after the surgery

Method of measurement

by goniometer

2**Description**

Range Of Motion of MP joint of the injured thumb

Timepoint

3 and 6 months after the surgery

Method of measurement

by goniometer

Secondary outcomes

empty

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

Intervention group: FPL tendon repair with tendon transfer

Category

Treatment - Surgery

2**Description**

Intervention group: FPL tendon repair with tendon graft
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Hazrat Fatemeh hospital
Full name of responsible person
Mehdi Tassallibakhsh
Street address
21th Ave., Yousefabad St.
City
Tehran
Province
Tehran
Postal code
1433933111
Phone
+98 21 8871 7272
Email
crtfatima@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Hossein Keivan
Street address
5th floor, Iran University of Medical Sciences, beside
of Milad Tower, Shahid Hemmat Highway
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8862 2703
Email
info@iums.ac.ir
Grant name
Grant code / Reference number
**Is the source of funding the same sponsor
organization/entity?**
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Mehdi Tassallibakhsh
Position
fellow
Latest degree
Specialist
Other areas of specialty/work
plastic and reconstructive surgery
Street address
Unit 4, No. 1, SoltaniAzar Alley, Ostad Hassan Banna
St. Heravi Sq.
City
Tehran
Province
Tehran
Postal code
1669645951
Phone
+98 21 2297 6769
Email
dr_tasallibakhsh@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Yousef Shafaei Khanghah
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Plastic and reconstructive surgery
Street address
21th. Ave., Yousefabad St., Hazrat Fatemeh hospital
City
Tehran
Province
Tehran
Postal code
1433933111
Phone
+98 21 8871 7272
Email
dr.yousefshafaei@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mehdi Tassallibakhsh

Position

fellow

Latest degree

Specialist

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dr_tasallibakhsh@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

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

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

Procedure description sheets and patient histories will be
shared after de-identification

When the data will become available and for how long

The access period starts 6 months after the results are
published

To whom data/document is available

For all academic institutions and researchers

Under which criteria data/document could be used

Use of data in accordance with ethical points in future
researches

From where data/document is obtainable

Refer to the researcher

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

The applicant can receive the documents within 15 days
after sending the request to the project manager's email.

Comments

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