

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of Extensor Digiti Minimi Tendon (EDM) transfer on Ulnar Deviation of the Little Finger in patients with ulnar nerve injury

Protocol summary

Study aim

Correction of ulnar deviation in patients with ulnar nerve injury by transferring the extensor digiti minimi tendon and then checking the amount of correction of the angle between the fifth and fourth finger by measuring the angle with a protractor

Design

A clinical trial without a control group and without blinding that is performed on 15 patients.

Settings and conduct

Patients with ulnar nerve injury rarely come to correct the deviation of the fifth finger, and this interventional surgery is performed very rarely. All surgeries are performed at Hazrat Fatemeh Zahra Hospital, affiliated to Iran University of Medical Sciences, by a professor of plastic surgery. The extensor digiti minime tendon will be separated from the fifth metacarpophalangeal joint and moved from the fifth compartment of the extensor to the fourth compartment and sutured on the radial side of the fifth metacarpophalangeal joint in the position of correcting the deviation of the fifth finger.

Participants/Inclusion and exclusion criteria

Patients with a previous history of ulnar nerve injury of the hand, who have deviation of the fifth finger due to the weakness of the hypothenar muscles, and have a desire to correct the deviation of the fifth finger.

Intervention groups

Transferring the extensor digiti minimi tendon from the fifth finger and moving that from it's extensor compartment.

Main outcome variables

The degree of correction of deviation of the fifth finger

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230430058028N1**

Registration date: **2024-01-31, 1402/11/11**

Registration timing: **retrospective**

Last update: **2024-01-31, 1402/11/11**

Update count: **0**

Registration date

2024-01-31, 1402/11/11

Registrant information

Name

Ali Saadati Kanafi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6653 1378

Email address

alisaadat60@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2023-05-20, 1402/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Extensor Digiti Minimi Tendon (EDM) transfer on Ulnar Deviation of the Little Finger in patients with ulnar nerve injury

Public title

The effect of Extensor Digiti Minimi Tendon (EDM)

transfer on Ulnar Deviation of the Little Finger

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients with a history of ulnar nerve injury and deviation of the fifth finger as a result Willingness of the patient to participate in the study
Exclusion criteria:
 Age less than 10 years old The patient's unwillingness to participate in the study

Age
From **10 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **15**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

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

Iran University of Medical Sciences. Shahid Hemmat Highway Tehran

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2021-09-05, 1400/06/14

Ethics committee reference number

IR.IUMS.FMD.REC.1400.365

Health conditions studied

1

Description of health condition studied

Wartenberg`s sign

ICD-10 code

G56.2

ICD-10 code description

Lesion of ulnar nerve

Primary outcomes

1

Description

The amount of fifth finger deviation correction

Timepoint

Measuring the deviation angle of the fifth finger before the intervention and 3 months after the intervention

Method of measurement

goniometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: performing surgery to transfer the extensor tendon of digital mini-me and move its extensor compartment from 5 to 4 and re-stitch the tendon to correct the fifth deviation, which is performed by a plastic surgeon professor. The patient will wear an extensor brace for three weeks and then be referred for 2 months of physical therapy. Three months after the surgery, the degree of angle change and correction of the deviation of the fifth finger will be measured with a goniometer.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Fatemeh Hospital

Full name of responsible person

Ali Saadati Kanafi

Street address

Hazrat Fatemeh Hospital; 21 Ave. Asad Abadi Street;

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Web page address
<https://crtfatima.iums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Reza Falak
Street address
Hemat Highway; next to Milad Tower; Iran University
of Medical Science
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 86701
Fax
+98 21 8862 2675
Email
Rezafalak@iums.ac.ir
Web page address

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
Ali Saadati Kanafi
Position
Plastic and Reconstructive surgery Fellowship
Latest degree
Specialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

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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

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information about the main outcome can be shared

When the data will become available and for how long

Access starts 6 months after results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

The use of the data is allowed under the condition that the names of the patients are kept confidential.

From where data/document is obtainable

Dr Ali Saadati Kanafi Mobile 00989128078138 email alisaadat60@gmail.com Hazrat Fatemeh Hospital. 21 Alley. Asad Abadi Ave. Tehran

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

The request to receive data will be answered within a maximum period of one week after receiving the request.

Comments