

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Comparison of active and passive rehabilitation on outcomes of the flexor tendons repair in zone II of the hand

Protocol summary

Summary

This study is designed to compare effect of two methods of active and passive rehabilitation on outcomes of flexor tendons repair in zone II of fingers of hand. It is a randomized and single blind clinical trial which will be done on 20 patients. Inclusion criteria are 15 to 60 years of age, sharp rupture of flexor tendons of fingers in zone II, referral in 72 h after injury, living in Tehran and suburbs and filling out the informed consent. Exclusion criteria include tendon rupture with fracture and crush injury of the tendon. Tendon repair surgery will be done on all patients with the same techniques by a single surgeon. After 48 h, the patients will be divided into two groups (10 patients with active rehabilitation and 10 patients with passive rehabilitation) by an occupational therapist based on the random number table. In both groups, the patients are treated with 24 sessions of occupational therapy protocols. Complications and range of motion, grip strength and pinch strength of the fingers will be evaluated by a surgeon and occupational therapist in 1, 2, 4, 6, 12 and 24 weeks and the results are recorded. Then, results including functional evaluation, costs, patient satisfaction and complication rates will be compared in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201310138177N8**

Registration date: **2013-11-06, 1392/08/15**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-11-06, 1392/08/15

Registrant information

Name

Mohammad Javad Fatemi

Name of organization / entity

Burn Research Center of Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-11-22, 1392/09/01

Expected recruitment end date

2015-11-22, 1394/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of active and passive rehabilitation on outcomes of the flexor tendons repair in zone II of the hand

Public title

Comparison of active and passive rehabilitation on outcomes of the flexor tendons repair in fingers of the hand

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. Fifteen to sixty years old patients 2.

Sharp rupture of flexor tendons of fingers in zone II 3. Referral in 72 h after injury 4. Living in Tehran and suburbs 5. Filling out the informed consent Exclusion criteria: 1. Tendon rupture with fracture 2. Crush injury of the tendon

Age

From **15 years** old to **60 years** old

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

Blinding (investigator's opinion)

Single 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 Tehran University of Medical Sciences

Street address

Central Department of Tehran University of Medical Sciences, Keshavarz Blvd, Tehran

City

Tehran

Postal code

1417653761

Approval date

2013-04-22, 1392/02/02

Ethics committee reference number

91-02-12-16749-67256

Health conditions studied

1

Description of health condition studied

Tendon repair

ICD-10 code

M66.3

ICD-10 code description

Spontaneous rupture of flexor tendon

Primary outcomes

1

Description

Grip strength

Timepoint

Weeks 1, 2, 4, 6, 12 and 24 after surgery

Method of measurement

Examination

2

Description

Range of motion

Timepoint

Weeks 1, 2, 4, 6, 12 and 24 after surgery

Method of measurement

Examination

3

Description

Pinch strength

Timepoint

Weeks 1, 2, 4, 6, 12 and 24 after surgery

Method of measurement

Examination

4

Description

Wound healing

Timepoint

Weeks 1, 2 and 4 after surgery

Method of measurement

Observation

5

Description

Cost

Timepoint

After ending intervention

Method of measurement

Calculation of dressing costs per group

6

Description

Patient satisfaction

Timepoint

After ending intervention

Method of measurement

Interview

Secondary outcomes

1

Description

Tendon rupture

Timepoint

Weeks 1, 2, 4, 6, 12 and 24 after surgery
Method of measurement
Examination

2

Description

Tendon adhesions

Timepoint

Weeks 1, 2, 4, 6, 12 and 24 after surgery

Method of measurement

Examination

3

Description

Infection

Timepoint

Weeks 1, 2 and 4 after surgery

Method of measurement

Observation

4

Description

Flap necrosis

Timepoint

Weeks 1, 2 and 4 after surgery

Method of measurement

Observation

5

Description

Edema

Timepoint

Weeks 1, 2 and 4 after surgery

Method of measurement

Observation

6

Description

Pain

Timepoint

Weeks 1, 2, 4, 6, 12 and 24 after surgery

Method of measurement

Visual Analogue Scale

7

Description

Contractures

Timepoint

Weeks 6, 12 and 24 after surgery

Method of measurement

Observation

8

Description

Scar

Timepoint

Weeks 12 and 24 after surgery

Method of measurement

Vancouver Scar Scale

Intervention groups

1

Description

Active rehabilitation: Full range of active flexion and extension of the operated finger under supervision of the occupational therapist; 3 movements in one session per day for 3 weeks

Category

Rehabilitation

2

Description

Passive rehabilitation: Full range of passive flexion of the finger (rubber band) and active extension by the patient under supervision of the occupational therapist; 3 movements in three sessions per day for 3 weeks

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Fatima Hospital

Full name of responsible person

Mohammad Javad Fatemi

Street address

Hazrat Fatima Hospital, Seyed Jamaledin Asadabadi Ave, Tehran

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Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Tehran University of Medical

Full name of responsible person

Akbar Fotouhi

Street address

Central Department of Tehran University of Medical Sciences, Keshavarz Blvd, Tehran

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 Tehran University of

Medical
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
Hazrat Fatima Hospital
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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