Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 injeury 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 Jamaleddin Asadabadi Ave, Tehran
City
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 Bvld, 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
Full name of responsible person
Mohammad Javad Fatemi
Position
Associate Professor of Plastic and Reconstructive Surgery
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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