

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### The Investigation of the Effect of Two Methods of Early Active and Passive Motion on Hand Function and Satisfaction in Patients with Flexor Tendon Injury in Zone 1 and 2

#### Protocol summary

##### Study aim

Comparison of the effect of Two Methods of Early Active and Passive Motion on Hand Function and Satisfaction in Patients with Flexor Tendon Injury in Zone 1 and 2

##### Design

30 patients with flexor tendon injury in zone 1 and 2 who have criteria for entering the study will be included in the study and will be randomly assigned to one of the two early active motion or early passive motion groups. The sample size will be 15 people per group.

##### Settings and conduct

This study is an experimental randomized clinical trial in which patients with flexor tendon zone 1 and 2 who have performed their medical (surgical) operations in Hazrat Fatemeh Hospital in Tehran have been studied and then randomization will be placed in one of the two groups of early active motion and early premature motion. The Strickland protocol will be implemented for the early active movement group and the modified Duran protocol for the early passive motion group. Interventions and evaluations will be done in the hospital.

##### Participants/Inclusion and exclusion criteria

Restoration of flexor tendon in zone 1 and 2; passing of time 4 to 2 days after surgery; similar surgery method; 12 year old calendar; non fracture and extensor tendon injury in the same finger; initial tendon repair; cognitive test score MMSE 21 or higher; Lack of psychological problems; lack of neurological and orthopedic diseases; Person's willingness to work together

##### Intervention groups

An early active motion group will use the Strickland protocol. And in the early passive motion group is used the modified Duran protocol.

##### Main outcome variables

hand function;satisfaction

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150721023277N7**

Registration date: **2018-08-14, 1397/05/23**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-08-14, 1397/05/23**

Update count: **0**

##### Registration date

2018-08-14, 1397/05/23

##### Registrant information

##### Name

Laleh Lajevardi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2222 8051

##### Email address

lajevardi.l@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-08-01, 1397/05/10

##### Expected recruitment end date

2019-03-01, 1397/12/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The Investigation of the Effect of Two Methods of Early Active and Passive Motion on Hand Function and Satisfaction in Patients with Flexor Tendon Injury in Zone 1 and 2

## Public title

The Investigation of the Effect of Two Methods of Early Active and Passive Motion in flexor tendon injury in zone 1 and 2

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Sharp tendon injuries Time lapse 4-2 days after surgery restoration of flexor tendon in Zone 1 and 2 Age 12 years old Not having injuries (fracture in the same limb, extensor tendon damage on the same finger) Not having psychological problems (problems that cause not cooperating with the implementation of therapeutic protocols) Having an acceptable level of cognitive performance, 21 or higher, in the Mini Mental Status Examination (MMSE) The initial repair of the tendon without the need for a transfer or graft tendon Not having a neurological disease (stroke, dementia, Parkinson, etc.) and orthopedic (arthritis and ...) Similar restoration method

### Exclusion criteria:

Unwillingness to continue cooperation

## Age

From 12 years old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Outcome assessor

## Sample size

Target sample size: 30

## Randomization (investigator's opinion)

Randomized

## Randomization description

In this study, simple randomization by individuals will be used based on table of random number.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

This study is designed as double-blind in which participants and assessor are not aware of being in control or intervention group.

## 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

School of Rehabilitation, Shahid Shahnazari Street, Madar Square, Mirdamad Blvd, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

15459-13487

#### Approval date

2017-10-27, 1396/08/05

#### Ethics committee reference number

IR.IUMS.FMD.REC 1396.9511355005

## Health conditions studied

### 1

#### Description of health condition studied

Flexor tendon injury in zone 1 and 2

#### ICD-10 code

M66.3

#### ICD-10 code description

Spontaneous rupture of flexor tendons

## Primary outcomes

### 1

#### Description

Score of hand function in Michigan hand outcomes questionnaire (MHQ)

#### Timepoint

Measure hand function at the beginning of the study (before the intervention), 8 weeks after intervention and after follow up (4 weeks)

#### Method of measurement

Michigan hand outcomes questionnaire (MHQ) to measure the hand function.

### 2

#### Description

Satisfaction in activity of daily living in the Canadian Occupational Performance Measure

#### Timepoint

Measuring satisfaction degree in activity of daily living at the beginning of the study (before the intervention), 8 weeks after the intervention and after follow up (4 weeks)

#### Method of measurement

Canadian Occupational Performance Measure Inventory to measure satisfaction in activity of daily living.

## Secondary outcomes

### 1

#### **Description**

Scale of range of motion from goniometer

#### **Timepoint**

Measuring the range of motion at the beginning of the study (before the intervention), 8 weeks after the start of the intervention and after the follow up (4 weeks)

#### **Method of measurement**

Goniometer to measure the range of motion

### 2

#### **Description**

Score the pain of the scale of the Visual Analogue Scale

#### **Timepoint**

Pain measurements at the beginning of the study (before the intervention), 8 weeks after the start of the intervention and after the follow up (4 weeks)

#### **Method of measurement**

Visual Analogue Scale to measure pain

### 3

#### **Description**

Disability Score in the Disability of the Arm, Shoulder and Hand Questionnaire

#### **Timepoint**

Measurement of disability at the beginning of the study (before the intervention), 8 weeks after the start of the intervention and after the follow-up period (4 weeks)

#### **Method of measurement**

Questionnaire for disability of the arm, shoulder and hand outcome questionnaire to measure disability

### 4

#### **Description**

Scale of gross motor performance in Box and Blocks test

#### **Timepoint**

Measurement of gross motor function 8 weeks after the start of the intervention and after the follow-up period (4 weeks)

#### **Method of measurement**

Box and Blocks test to measure gross motor performance

### 5

#### **Description**

Fine motor performance score in Purdue Pegboard Test

#### **Timepoint**

Measurement of fine motor function 8 weeks after the start of the intervention and after the follow-up period (4 weeks)

#### **Method of measurement**

Purdue pegboard test to measure fine motor performance

### 6

#### **Description**

Score of grasp power from dynamometer

#### **Timepoint**

Measuring the grasp power 8 weeks after the start of the intervention and after the follow-up period (4 weeks)

#### **Method of measurement**

Dynamometer to measure grasp power

### 7

#### **Description**

Score of Power pinch of pinch gauge

#### **Timepoint**

Measure the power of the pinch 8 weeks after the start of the intervention and after the follow up (4 weeks)

#### **Method of measurement**

Pinch gauge to measure pinch power

## Intervention groups

### 1

#### **Description**

Intervention group: The clients will be referred to the occupational therapist within 24-24 hours after surgery. In this group, regular rehabilitation programs and the Strickland protocol will be implemented. The treatment sessions will be performed by the therapist for 45 minutes, 3 days a week for 8 weeks. In this method, two splints are used: 1: Dorsal Block Splint, which is made of plaster, and wrist joint in 20 degrees of flexion, metacarpophalangeal at 50 degrees of flexion and interphalangeal in the extension and most of the time, 2: Splint is a thermoplastic training. The ankle part is hinged and allows full flexion to the wrist, metacarpophalangeal and interphalangeal joints, but limits the wrist at 30 degrees of extension, metacarpophalangeal at 60 degrees and interphalangeal at 25 degrees of flexion. Week 4-0: Every hour the exercises will be performed by 15 times repetitive exercises in splint Dorsal Block and the flexion Place and Hold practice with 15 repetitions in splint, These exercises will be presented in writing and videos recorded for them at home. Week 8-4: splint training will be lifted, but splint Dorsal Block will be covered except during training, and exercises will be done every 2 hours. At 6-5 weeks, the blocking and hook fist exercises will be performed. 7-8 weeks of progressive resistance exercises and daily routine activities will be added. At week 14, complete resistance exercises and heavy daily activities will be performed.

#### **Category**

Rehabilitation

### 2

#### **Description**

Intervention group: Intervention group: The client will be referred to the occupational therapist within 24-24 hours after surgery. A therapist will be performed a traditional rehabilitation program modified Duran protocol of 40

minutes, three days per week, for eight weeks. In this group, a dorsal block splint will be used, which will place the wrist joint at 20 ° flexion and metacarpophalangeal at 50 ° flexion and allowing the interphalangeal joints to be fully extended. At week 0-3, the client each hour will carry out the joints passive flexion and active extensions exercises . Week 5-4: In addition to the previous exercises active wrist movements are performed , week 7-6:Light activities of daily living and blocking exercises will be added.Progressive resistance exercises will begin from the 8 week. In addition, these exercises will be provided in writing and videos recorded to perform at home.

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Hospital of Hazrat Fatemeh

##### Full name of responsible person

Leila Mirzaei

##### Street address

Hazrat Fatemeh Hospital, 21st Street, Yousef Abad, Tehran.

##### City

Tehran

##### Province

Tehran

##### Postal code

13393111

##### Phone

+98 21 8871 7272

##### Email

SAITDM95@GMAIL.COM

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Seyyed Kazam Malakoti

##### Street address

School of Rehabilitation, Shahid Shahnazari Street, Madar Square, Mirdamad Blvd, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

15459-13487

##### Phone

+98 21 2222 8051

##### Email

Lajevardi.l@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

Laleh Lajevardi

##### Position

Associate Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Occupational Therapy

##### Street address

School of Rehabilitation, Shahid Shahnazari Street, Madar Square, Mirdamad Blvd, Tehran

##### City

Tehran

##### Province

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##### Postal code

15459-13487

##### Phone

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##### Email

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Iran University of Medical Sciences

##### Position

Laleh Lajevardi

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Occupational Therapy

##### Street address

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Laleh Lajevardi  
**Position**  
Associate Professor  
**Latest degree**  
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**Other areas of specialty/work**  
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**Street address**  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

playgerism

### 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

Information on the primary and secondary outcome measures

### When the data will become available and for how long

After publishing the articles

### To whom data/document is available

Researchers intending to research in this field.

### Under which criteria data/document could be used

Obtaining written permission from the research team -  
Mention the source of information

### From where data/document is obtainable

Mina Khosravi: School of Rehabilitation, Shahid Shahnazari Street, Madar Square, Mirdamad Blvd, Tehran. Email Address: khosravi.mina73@gmail.com -Dr. Laleh Lajevardi: School of Rehabilitation, Shahid Shahnazari Street, Madar Square, Mirdamad Blvd, Tehran. Email Address: Lajevardi.l@iums.ac.i

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

After sending the email to the researcher and requesting the document, the researcher will request the opinion of other members of the research team regarding the provision of this information and, if the members agree, the documents will be sent as soon as possible but sending the documents requires the acceptance of the criteria mentioned above.

### Comments