

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of Extensor tendon repair methods with surgiwrap and without surgiwrap, as regards the rate of adhesion in patients with hand extensor tendon injury

#### Protocol summary

##### Study aim

To compare extensor tendon repair methods (with vs. without Surgiwrap application) regarding adhesion in patients with hand extensor tendon injury.

##### Design

Phase 3 randomized controlled clinical trial, with two parallel groups, single-blind, that is performed on 80 tendon samples.

##### Settings and conduct

This study is performed in Shahid Rahnemoun Hospital and Shahid Sadoughi Hospital in Yazd. Eligible patients entered the study after obtaining informed consent and are not aware of their assignment to any of the intervention or control groups.

##### Participants/Inclusion and exclusion criteria

All patients aged 18 to 65 years, who could repair the tendon directly without shortening and surgical indication for repair and also lacked: uncontrolled diabetes, multiple injuries, simultaneous incision of flexors with nerves and arteries and inability to repair; After obtaining informed consent until reaching the final specified sample size (80 tendon samples), were included in the study.

##### Intervention groups

In the control group, the standard of care (SOC) method is used to treat patients. The intervention group receives the SOC and placing a barrier between the skin and the tendon.

##### Main outcome variables

Tendon adhesion is assessed with the Miller Scoring Scale at the first visit, weeks 3, 6, and 12 after splint removal.

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20180627040252N3**

Registration date: **2022-06-17, 1401/03/27**

Registration timing: **retrospective**

Last update: **2022-06-17, 1401/03/27**

Update count: **0**

#### Registration date

2022-06-17, 1401/03/27

#### Registrant information

##### Name

Abbas Abdoli Tafti

##### Name of organization / entity

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Iran (Islamic Republic of)

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#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2019-09-03, 1398/06/12

#### Expected recruitment end date

2020-01-10, 1398/10/20

#### Actual recruitment start date

2019-09-03, 1398/06/12

#### Actual recruitment end date

2019-10-27, 1398/08/05

#### Trial completion date

2020-02-06, 1398/11/17

#### Scientific title

Comparison of Extensor tendon repair methods with surgiwrap and without surgiwrap, as regards the rate of

adhesion in patients with hand extensor tendon injury

**Public title**

Surgiwrap in tendon repair

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Zone 6 extensor tendon injury Ability to repair the tendon directly and without shortening Surgical repair indication Completion of informed consent

**Exclusion criteria:**

Patients with uncontrolled diabetes Multiple injuries Simultaneous rupture of flexors with nerves and arteries Inability to direct repair Metacarpal fracture Crush injury

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **40**

More than 1 sample in each individual

Number of samples in each individual: **2**

Each participant in the study may have suffered damage to several extensor tendons. Each extensor tendon in these individuals is considered as a sample for our study and is randomly assigned to the study groups.

Actual sample size reached: **40**

More than 1 sample in each individual

Actual sample size in each individual: **2**

Each of the extensor tendons of the hand in patients is considered as a sample and is randomly assigned to intervention groups.

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients entered the study after obtaining informed consent until reaching the final specified sample size (80 tendon samples). The sample size was 40 patients for 95% confidence level and 80% test power and 9.1 standard deviations for the main outcome of the motion difference. Because most patients had rupture of several extensor tendons; 80 specimens of extensor tendons were considered except for the thumb extensors. Each patient participating in the study was assigned to two intervention groups using block randomisation until the extensor tendon sample size was completed in a ratio of 1: 1.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

In this study, all participants are aware of participating in this study and enter the study with their consent. participants are unaware of which group of this study they are in. The lead researcher, health care personnel, data collection officials, and those who evaluate the outcome are aware of the grouping of patients. Those

who prepare the draft of the article are unaware of the groupings if they do not cooperate in the above cases.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research Ethics Committees of School of Medicine-Shahid Sadoughi University of Medical Sciences

**Street address**

Bahonar Square

**City**

Yazd

**Province**

Yazd

**Postal code**

8916978477

**Approval date**

2019-09-01, 1398/06/10

**Ethics committee reference number**

IR.SSU.MEDICINE.REC.1398.175

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

Laceration of extensor muscle, fascia or tendon of other finger at wrist or hand level

**ICD-10 code**

NC57.31

**ICD-10 code description**

Laceration of extensor muscle, fascia or tendon of other finger at wrist or hand level

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

Tendon adhesion

**Timepoint**

At the first visit and in the third, sixth and twelfth weeks after splint removal.

**Method of measurement**

Miller's scoring system.

**Secondary outcomes**

empty

## Intervention groups

### 1

#### Description

Control group: Patients were referred to the operating room of the hospital for surgery and after randomly assigning them to the two intervention groups by operating room admission, in both groups (control and intervention) the standard treatment method (SOC) is as follows: Patients undergo local anaesthesia (5% lidocaine) and initial repair, and an arm tourniquet is used. Wounds are examined and washed with normal saline and the tendons cut are repaired by a surgeon with Prolen 3.0 and end-to-end running (SOC) method. The skin is then wrapped in nylon 5.0. All patients' hands are immobilized for 3 to 6 weeks (4 weeks) by static splint in the position of 40-45 degrees of extension in the wrist, 20 degrees of flexion in the metacarpophalangeal joint, and zero degrees of flexion of the interphalangeal joints to protect the repair site. From there, the protected active movement begins.

#### Category

Treatment - Surgery

### 2

#### Description

Intervention group: Patients were referred to the operating room of the hospital for surgery and after randomly assigning them to the two intervention groups by operating room admission, in both groups (control and intervention) the standard treatment method (SOC) is as follows: Patients undergo local anaesthesia (5% lidocaine) and initial repair, and an arm tourniquet is used. Wounds are examined and washed with normal saline and the tendons cut are repaired by a surgeon with Prolen 3.0 and end-to-end running (SOC) method. In the intervention group (SOC + S) after tendon repair, (Barrier (Surgiwrap) is placed between the skin and tendon and is sewn on 4 sides of the tendon with 05 sutures. so that, each side cover one centimetre more than the repair site. The skin is then wrapped in nylon 5.0. All patients' hands are immobilized for 3 to 6 weeks (4 weeks) by static splint in the position of 40-45 degrees of extension in the wrist, 20 degrees of flexion in the metacarpophalangeal joint, and zero degrees of flexion of the interphalangeal joints to protect the repair site. From there, the protected active movement begins.

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Sadoughi hospital

##### Full name of responsible person

Mortaza Rezaie

##### Street address

Shahid Sadoughi Hospital, Ebne Sina Street, Shahid Ghandi Blvd

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### 2

#### Recruitment center

##### Name of recruitment center

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##### Full name of responsible person

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Yazd University of Medical Sciences

##### Full name of responsible person

Masoud Mirzaei

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#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Yazd 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**  
Bandare-abbas University of Medical Sciences  
**Full name of responsible person**  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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## 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

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available