

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 2026

### Evaluation effect of amniotic membrane tendon wrapping in final results of zone 6 extensor tendon repair

#### Protocol summary

##### Study aim

Evaluation effect of amniotic membrane tendon wrapping in final results of zone 6 extensor tendon repair

##### Design

Double-blind, randomized controlled clinical trial

##### Settings and conduct

Patients with rupture of the extensor tendon in zone 6 following penetrating trauma visiting 15 Khordad hospital are randomly allocated to two groups. In both groups, The tendon is repaired by end-to-end suture with 4-0 nylon using a modified Kessler technique. In the intervention group, the repair site was wrapped with an allogenic human amniotic membrane. In both groups functional outcome is determined by the Quick DASH score questionnaire at the end of the 6-month follow-up period.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Written informed consent to undergo the surgical procedure Rupture of extensor tendon in zone 6 following penetrating trauma Exclusion criteria: immunosuppression, , allergy history, patients with a past medical history of incision or surgical repair on the upper limb

##### Intervention groups

Intervention group: the tendon was repaired by end-to-end suture with 4-0 nylon using a modified Kessler technique. The repair site was wrapped with an allogenic human amniotic membrane prepared from Parsa Teb Iran in a size of 3 × 3 cm. The tendon was repaired by end-to-end suture with 4-0 nylon using a modified Kessler technique. (without wrapping with an allogenic human amniotic membrane).

##### Main outcome variables

Patient's ability to do daily activities based on the Quick DASH score, Patient's ability to work based on the Quick DASH score, Patient's ability to do sporting activities based on the Quick DASH score.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20110522006552N2**

Registration date: **2022-07-27, 1401/05/05**

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

Last update: **2022-07-27, 1401/05/05**

Update count: **0**

##### Registration date

2022-07-27, 1401/05/05

##### Registrant information

##### Name

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8890 1108

##### Email address

esmail\_hassanpour@yahoo.com

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2022-05-31, 1401/03/10

##### Expected recruitment end date

2022-12-01, 1401/09/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation effect of amniotic membrane tendon

wrapping in final results of zone 6 extensor tendon repair

## Public title

Amniotic membrane tendon wrapping in tendon repair

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Written informed consent to undergo the surgical procedure Rupture of flexor tendon in zone 6 following penetrating trauma

### Exclusion criteria:

immunosuppression allergy history patients with past medical history of incision or surgical repair on the upper limb

## Age

No age limit

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Investigator
- Outcome assessor

## Sample size

Target sample size: 30

## Randomization (investigator's opinion)

Randomized

## Randomization description

After explaining the study groups to the patients and obtaining informed consent to participate in the study, randomization was done by drawing a card indiscriminately from an envelope with an equal number of cards labeled with or without amniotic membrane tendon wrapping before the patient started therapy.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

In our study, patients, investigators, and the assessors of the outcomes are also unaware of the study groups. After explaining the study groups to the patients and obtaining informed consent to participate in the study, randomization was done by drawing a card indiscriminately from an envelope with an equal number of cards labeled with or without amniotic membrane tendon wrapping before the patient started therapy.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

## 1

### Ethics committee

#### Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

#### Street address

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran.

#### City

Tehran

#### Province

Tehran

#### Postal code

1989934148

### Approval date

2022-04-26, 1401/02/06

### Ethics committee reference number

IR.SBMU.MSP.REC.1401.049

## Health conditions studied

## 1

### Description of health condition studied

tendon rupture

### ICD-10 code

S66

### ICD-10 code description

Injury of muscle, fascia and tendon at wrist and hand level

## Primary outcomes

## 1

### Description

Patients score based on Quick DASH score questionnaire

### Timepoint

before intervention and 6 months after intervention

### Method of measurement

The Quick disabilities of the arm, shoulder, and hand (DASH) outcome questionnaire.

## Secondary outcomes

## 1

### Description

adhesion formation

### Timepoint

before intervention and 6 months after intervention

### Method of measurement

physical examination

## 2

### Description

infection

### Timepoint

before intervention and 6 months after intervention

**Method of measurement**

physical examination

**3****Description**

re-rupture of the tendon

**Timepoint**

before intervention and 6 months after intervention

**Method of measurement**

physical examination

**4****Description**

Tendon recovery time

**Timepoint**

before intervention and 6 months after intervention

**Method of measurement**

physical examination

**Intervention groups****1****Description**

Intervention group: The tendon is repaired by end-to-end suture with 4-0 nylon using a modified Kessler technique. The repair site was wrapped with an allogenic human amniotic membrane prepared from Parsa Teb Iran in a size of 3 × 3 cm.

**Category**

Treatment - Surgery

**2****Description**

Control group: The tendon is repaired by end-to-end suture with 4-0 nylon using a modified Kessler technique (without wrapping with an allogenic human amniotic membrane ).

**Category**

Treatment - Surgery

**Recruitment centers****1****Recruitment center****Name of recruitment center**

15 Khordad Hospital

**Full name of responsible person**

Esmail Hassanpour

**Street address**

15 Khordad Hospital, Azodei Street , KarimKhan Zand , Tehran, Iran

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Esmail\_hassanpour@yahoo.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Seyed Ali Ziai

**Street address**

Shahid Beheshti University of Medical Sciences, Velenjak, Shahid Chamran Highway, Tehran, Iran

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19839-63113

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+98 21 2243 9770

**Email**

Intl\_office@sbmu.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Hojjat Layegh

**Position**

Resident

**Latest degree**

Specialist

**Other areas of specialty/work**

plastic surgery

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Shahid Beheshti University of Medical Sciences, Velenjak, Shahid Chamran Highway, Tehran, Iran

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layeghhojjat@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Esmail Hassanpour  
**Position**  
Professor  
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Subspecialist  
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## Person responsible for updating data

### Contact

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Shahid Beheshti University of Medical Sciences  
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Resident  
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layeghhojjat@gmail.com

## 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

All collected demographic data and primary and secondary outcomes are going to be shared after de-identification of the participants.

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

These data files will become available starting 6 months after publication.

### To whom data/document is available

The deidentified IPD and additional supporting information/documents will be available for people working in academic institutions

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

None.

### From where data/document is obtainable

To access the data files applicant can talk to Dr. Hojjat Layegh, resident of plastic surgery at Shahid Beheshti University of Medical Sciences. Address: Shahid Beheshti University of Medical Sciences, Velenjak, Shahid Chamran Highway, Tehran, Iran Postal code: 1985717443 Email address:layeghhojjat@gmail.com Phone number: 0098 21 2243 9982 Mobile number: 00989120201655

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

The applicants should follow Shahid Beheshti University of Medical Sciences process and protocols for accessing the data files.

### Comments