

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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Email

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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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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Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
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Esmail Hassanpour
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Professor
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Person responsible for updating data

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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