Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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
City
Tehran
Province
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Postal code
1598764514
Phone
+98 21 8894 3434
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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Tehran
Province
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Postal code
19839-63113
Phone
+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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Professor
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Person responsible for updating data

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Latest degree
Specialist
Other areas of specialty/work
Plastic surgery
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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