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
Country
Iran (Islamic Republic of)
Phone
+98 35 3522 2304
Email address
aabdoli2000@mail.ssu.ac.ir

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

City

Yazd

Province

Yazd

Postal code

8915887856

Phone

+98 35 3183 3550

Email

info@ssu.ac.ir

2

Recruitment center

Name of recruitment center

Shahid rahnemoun hospital

Full name of responsible person

Mortaza Rezaie

Street address

Taleghani Blvd

City

Yazd

Province

Yazd

Postal code

8913814396

Phone

+98 35 3626 0001

Email

rahnamoon@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Masoud Mirzaei

Street address

Bahonar Square

City

Yazd

Province

Yazd

Postal code

8916978477

Phone

+98 35 3726 3733

Email

mmirzaei@ssu.ac.ir

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
Morteza Rezaei

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Orthopedics

Street address
Office of the Surgery Group, Shahid Mohammadi Hospital, Boulevard of the Islamic Republic of Iran, Bandar Abbas

City
Bandar Abbas

Province
Hormozgan

Postal code
7916613885

Phone
+98 912 063 5468

Email
rezaie.mortaza@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Abbas Abdoli Tafti

Position
Assistant professor

Latest degree
Subspecialist

Other areas of specialty/work
Hand Surgery

Street address
Shahid Sadougi hospital, Ebne Sina street, Shahid Ghandi BLvd

City
Yazd

Province
Yazd

Postal code
8916886938

Phone
+98 35 3822 4000

Email
aabdoli2000@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Bandare-abbas University of Medical Sciences

Full name of responsible person
Dariush Hooshyar

Position
Student of Medicine

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

Street address
Faculty of Medicine, Pardis unit of Hormozgan University of Medical Sciences, End of Imam Hossein Blvd., Bandar Abbas, Iran

City
Bandar Abbas

Province
Hormozgan

Postal code
7919693116

Phone
+98 990 038 7226

Email
dariush.hooshyar@gmail.com

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