

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of the results of vitamin C injection in flexor tendon repair in zone II

#### Protocol summary

##### Study aim

In this study, we investigate the use of vitamin C in flexor tendon repair and compare its complications and effectiveness with non-injection repair method.

##### Design

A clinical trial with a control group, with parallel randomized groups, was used to assign numbers to patients based on random number table numbers for randomization.

##### Settings and conduct

The surgeon and the patient are aware of the methods of surgical treatment, but the person who performs the patients' functional measurements after surgery is blind to the type of surgical procedure of the patients.

##### Participants/Inclusion and exclusion criteria

Patient with a laceration in zone 2; immune system defects; patients with concomitant fractures; patients with crush injury; patients with a closed tendon injury

##### Intervention groups

In this study, we will repair tendon damage in group A using vitamin C injections and group B without injections.

##### Main outcome variables

Success rate and range of motion are the main results

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211201053235N7**

Registration date: **2022-06-25, 1401/04/04**

Registration timing: **prospective**

Last update: **2022-06-25, 1401/04/04**

Update count: **0**

##### Registration date

2022-06-25, 1401/04/04

#### Registrant information

##### Name

Meisam Jafari Kafiabadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2271 8000

##### Email address

dr.jafari8567@yahoo.com

#### Recruitment status

##### Recruitment complete

#### Funding source

##### Expected recruitment start date

2022-07-23, 1401/05/01

##### Expected recruitment end date

2023-07-23, 1402/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

#### Scientific title

Evaluation of the results of vitamin C injection in flexor tendon repair in zone II

#### Public title

Flexor tendon repair in zone II

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patients with tendon injury in zone 2

##### Exclusion criteria:

Immune system defects Close tendon injury Crush injury Concomitant fracture

#### Age

From **20 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

No information

**Sample size**

Target sample size: 30

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

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

empty

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

Ethical Committee of Shahid Beheshti University of Medical Sciences

**Street address**

Arabi Ave., Daneshjoo Blvd., Velenjak, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

19839631113

**Approval date**

2022-04-24, 1401/02/04

**Ethics committee reference number**

4.1401.REC.RETECH.SBMU.IR

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

Tendon injury

**ICD-10 code**

S60

**ICD-10 code description**

Superficial injury of wrist, hand and fingers

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

Range of motion

**Timepoint**

3 months after surgery

**Method of measurement**

Examination by a surgeon

**2****Description**

Tendon rupture

**Timepoint**

2 weeks and 3 months after surgery

**Method of measurement**

Examination by a surgeon

**Secondary outcomes**

empty

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

Intervention group: Patients with laceration in zone 2 of the hand, after repairing the flexor tendon and closing the wound, 5 cc of vitamin C is injected at the site of repair and then plaster cast is performed. The next day after surgery, the passive flexion and active extension movements for the patients begin, and 5 weeks later, the patient's cast was opened and physiotherapy is requested.

**Category**

Treatment - Surgery

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

Shohada e Tajrish Hospital

**Full name of responsible person**

Meisam Jafari Kafiabadi

**Street address**

Shohada-e-Tajrish Hospital, Qods Sq., Tajrish, Tehran, Iran

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1989934148

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dr.jafari8567@yahoo.com

**Sponsors / Funding sources**

## 1

### Sponsor

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr. Afshin Zarghi

**Street address**

Arabi Ave, Daneshjoo Blvd., Velenjak, Tehran, Iran.

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mpd@sbmu.ac.ir

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

No

**Title of funding source**

Research affairs of 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**

Meisam Jafari Kafiabadi

**Position**

Assistant professor

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Orthopedics

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### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Meisam Jafari Kafiabadi

**Position**

Associate professor

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Orthopedics

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### Person responsible for updating data

**Contact****Name of organization / entity**

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**Full name of responsible person**

Farsad biglari

**Position**

Associate professor

**Latest degree**

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**Other areas of specialty/work**

Orthopedics

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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**

After finishing patient recruitment

**When the data will become available and for how**

long

After finishing patient recruitment

**To whom data/document is available**

After finishing patient recruitment

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

After finishing patient recruitment

**From where data/document is obtainable**

After finishing patient recruitment

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

After finishing patient recruitment

**Comments**