# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Nov 2026

## The effect of drain application on outcome of open carpal tunnel release

## Protocol summary

**Study aim**
Evaluation of prognosis improvement in patients undergoing carpal tunnel release surgery after using drain.

**Design**
Clinical trials with control group, randomized with parallel groups

**Settings and conduct**
This study is being conducted at Shahid Doctor Rahnamoon Hospital. Patients with carpal tunnel syndrome are enrolled Based on the criteria for entering the study and are randomly assigned to two groups of 31 patients. Blinding is not done. Patients in each of the 2 groups after the carpal tunnel release surgery are evaluated through examination, visual analogue scale and pinch strength.

**Participants/Inclusion and exclusion criteria**
Patients referred to the orthopedic clinic of Shahid Doctor Rahnemoon Hospital who have severe carpal tunnel syndrome confirmed by clinical examination and nerve and muscle or with Moderate carpal tunnel syndrome, who did not respond to conservative treatment, enter the study with informed consent. Patients who simultaneously undergo surgery in addition to releasing the carpal tunnel, Patients with intraoperative Iatrogenic vascular injury and Patients with a history of anticoagulation therapy Or coagulation disorders are excluded.

**Intervention groups**
Intervention group: For patients in this group after the release of the carpal tunnel Drainage will be used. Control group: Patients in this group after the operation will not be used of the drain.

**Main outcome variables**
Bleeding and hematoma; Pain; Pinch strength

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20161225031559N3**
Registration date: **2018-10-17, 1397/07/25**
Registration timing: **registered_while_recruiting**

Last update: **2018-10-17, 1397/07/25**
Update count: **0**

**Registration date**
2018-10-17, 1397/07/25

**Registrant information**

**Name**
Seyed Hossein Saeed-Banadaky

**Name of organization / entity**
Shahid Sadoughi Medical University

**Country**
Iran (Islamic Republic of)

**Phone**
+98 35 3626 0001

**Email address**
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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2018-09-23, 1397/07/01

**Expected recruitment end date**
2019-09-23, 1398/07/01

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
The effect of drain application on outcome of open carpal tunnel release

**Public title**
The effect of drain application on outcome of surgery

**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Patients with severe carpal tunnel syndrome confirmed by clinical examination and electrodiagnostic testing. Patients with Moderate carpal tunnel syndrome who did not respond to conservative treatment Informed consent
**Exclusion criteria:**
Patients who simultaneously undergo surgery in addition to releasing the carpal tunnel. Patients with intraoperative Iatrogenic vascular injury Patients with a history of anticoagulation therapy  Or coagulation disorders.
**Age**
From **25 years** old to **70 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **62**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
In this study through simple random method with the table of random numbers patients assigned to two groups
**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**
Ethics committee of Yazd Shahid Sadoughi University of Medical Sciences
**Street address**
Yazd Shahid Sadoughi university of medical sciences, Bahonar Sq, Yazd.
**City**
Yazd
**Province**
Yazd
**Postal code**
8916978477
**Approval date**
2018-04-29, 1397/02/09
**Ethics committee reference number**
IR.SSU.MEDICINE.REC.1397.090

## Health conditions studied

### 1

**Description of health condition studied**
Carpal Tunnel Syndrome
**ICD-10 code**
G56.0
**ICD-10 code description**
Carpal tunnel syndrome

## Primary outcomes

### 1

**Description**
The extent of bleeding and hematoma
**Timepoint**
2 days after surgery
**Method of measurement**
The extent of bleeding on the dressing gauze and Expert examination

## Secondary outcomes

### 1

**Description**
Postoperative pain
**Timepoint**
2, 4 and 6 weeks after surgery
**Method of measurement**
The visual analogue scale

### 2

**Description**
Pinch strength
**Timepoint**
2, 4, 6 months after surgery
**Method of measurement**
Pinch meter

## Intervention groups

### 1

**Description**
Intervention group: For patients in this group after the release of the carpal tunnel Drain will be used.
**Category**
Treatment - Devices

### 2

**Description**
Control group: Patients in this group after the operation will not be used of the drain.

**Category**
Treatment - Devices

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Shahid Doctor Rahnemoon Hospital
**Full name of responsible person**
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Yazd University of Medical Sciences
**Full name of responsible person**
Masoud Mirzaei
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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**
Yazd University of Medical Sciences
**Full name of responsible person**
Maziar Malekzadeh
**Position**
Resident
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## Person responsible for scientific inquiries

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Assistant Professor
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## Person responsible for updating data

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**Full name of responsible person**
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**Position**
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**Latest degree**
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**Other areas of specialty/work**
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**Province**
Yazd

**Postal code**
8913814396

**Phone**
+98 35 3626 0000

**Email**

## 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