

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### effect of local tranexamic acid in prevention of hematoma formation and swelling after surgery for carpal tunnel syndrome

#### Protocol summary

##### Summary

In this double blinded clinical trial, 50 patients with carpal tunnel syndrome requiring surgery will be randomly divided into two groups. In the intervention group, after complete hemostasis and tourniquet removal tranexamic acid will be introduced to the wound via a syringe, after which the wound is irrigated with normal saline. In the control group, placebo will be used. After surgery the patients will be followed in determined intervals and data registered in forms.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201605242115N4**  
Registration date: **2017-08-01, 1396/05/10**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-08-01, 1396/05/10

##### Registrant information

##### Name

Ali Reza Saied

##### Name of organization / entity

Kerman Neuroscience research center, Kerman  
University of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 1247 6432

##### Email address

arsaied@kmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Kerman University of Medical Sciences

##### Expected recruitment start date

2017-10-01, 1396/07/09

##### Expected recruitment end date

2018-10-22, 1397/07/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

effect of local tranexamic acid in prevention of hematoma formation and swelling after surgery for carpal tunnel syndrome

##### Public title

effect of local tranexamic acid in prevention of hematoma formation and swelling after surgery for carpal tunnel syndrome

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

inclusion criteria: 1. informed consent for entrance to trial 2. Carpal tunnel syndrome diagnosis requiring surgery exclusion criteria: 1.history of coagulation disorder 2.bilateral surgery 3.hypersensitivity to tranexamic acid

##### Age

No age limit

##### Gender

Both

##### Phase

2-3

##### Groups that have been masked

No information

##### Sample size

Target sample size: **50**

**Randomization (investigator's opinion)**

Randomized

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

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

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

empty

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

Kerman University of Medical sciences

**Street address**

22 Bahman Blvd.

**City**

Kerman

**Postal code****Approval date**

2017-06-20, 1396/03/30

**Ethics committee reference number**

IR.KMU.1396.1721

**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**

hematoma

**Timepoint**

day after the operation, second and fourth week, 3 months after the operation

**Method of measurement**

Wrist circumference measurement

**Secondary outcomes****1****Description**

grip power

**Timepoint**

first, second and third month after the operation

**Method of measurement**

Jammar Dynamometer

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

In the intervention group 1 ampule of tranexamic acid is injected into flexor sheet.

**Category**

Prevention

**2****Description**

In the control group normal saline is used.

**Category**

Treatment - Drugs

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

Shafa Hospital

**Full name of responsible person****Street address****City**

Kerman

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Kerman University of Medical sciences

**Full name of responsible person**

Dr Alireza Saied

**Street address**

Dr bahonar Hospital

**City**

Kerman

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

Yes

**Title of funding source**

Kerman University of Medical sciences

**Proportion provided by this source**

100

**Public or private sector**

empty

**Domestic or foreign origin**

empty

**Category of foreign source of funding**

*empty*  
**Country of origin**  
**Type of organization providing the funding**  
*empty*

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## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
Alireza Saied  
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Assistant Profesor of orthopedics  
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## Person responsible for scientific inquiries

### Contact

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Assistant Professor  
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## Person responsible for updating data

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

*empty*  
**Study Protocol**  
*empty*  
**Statistical Analysis Plan**  
*empty*  
**Informed Consent Form**  
*empty*  
**Clinical Study Report**  
*empty*  
**Analytic Code**  
*empty*  
**Data Dictionary**  
*empty*