Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Neurosceince research center, Kerman University of medical sciecnes

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 afher the operation
Method of measurement
Wrsit 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

Person responsible for general inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Alireza Saied

Position

Assistant Profesor of orthopedics

Other areas of specialty/work

Street address

Dr Bahonar Hospital

City

Kerman

Postal code

Phone

+98 34 1223 5011

Fax

Email

arsaiedmd@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical sciences

Full name of responsible person

Dr Alireza Saied

Position

Assistant Professor

Other areas of specialty/work

Street address

Orthopedics Dept.

City

Kerman

Postal code

Phone

+98 34 3223 5011

Fax

Email

arsaiedmd@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr Alireza Saied

Position

Assistant Professor of Orthopedics

Other areas of specialty/work

Street address

Orthopedics Dept.

City

Kerman

Postal code

Phone

+98 34 3223 5011

Fax

Email

arsaiedmd@yahoo.com

Web page address

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