

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Evaluation of the effect of topical tranexamic acid administration in preventing hematoma, swelling and pain after carpal tunnel syndrome surgery

Protocol summary

Study aim

Determining the effect of local tranexamic acid on post operation of carpal tunnel syndrome hematoma, swelling and pain .

Design

A clinical trial with a control group with a parallel group, triple blind, randomized phase 3 on 52 patients will be used for randomization using the rand function of Excel software.

Settings and conduct

This study is conducted in Besat Hospital in Hamadan, on patients with bilateral carpal tunnel syndrome who are candidates for surgery, in a triple-blind manner. All surgeries will be performed by one surgeon. On the intervention side, after the surgery, Transgamic acid is injected into the flexor sheet, but on the control side, after the surgery, normal saline is used inside the flexor sheet. day and will receive acetaminophen. The duration of the surgery, the amount of blood lost during the surgery and the hematoma and other surgical outcomes will be recorded in the checklist on the day after the operation, the second week and the fourth week and three months after the operation.

Participants/Inclusion and exclusion criteria

Patients with bilateral carpal tunnel syndrome. Inclusion criteria in the study: not using anti-anxiety and hypnotic drugs and painkillers and hemoglobin >10. Conditions of non-entry: history of coagulopathy, history of bilateral surgery, Allergy to tranexamic acid, contraindication for spinal anesthesia and allergy to anesthetics and other drugs.

Intervention groups

In the first group, in the intervention side, after the end of the surgery, Transgamic acid will be injected into the flexor sheet, but in the control side, after the end of the surgery, normal saline will be injected inside the flexor sheet.

Main outcome variables

The main outcomes include hematoma, swelling and pain, which will be recorded in the checklist on the day post operation, the second week and the fourth week and three months after the operation.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151123025202N32**

Registration date: **2023-10-24, 1402/08/02**

Registration timing: **prospective**

Last update: **2023-10-24, 1402/08/02**

Update count: **0**

Registration date

2023-10-24, 1402/08/02

Registrant information

Name

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Name of organization / entity

Hamedan University of Medical Of Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01

Expected recruitment end date

2024-08-22, 1403/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of topical tranexamic acid administration in preventing hematoma, swelling and pain after carpal tunnel syndrome surgery

Public title

Prevention of hematoma, swelling and pain after carpal tunnel syndrome surgery with tranexamic acid

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of bilateral carpal tunnel syndrome that requires surgery Not using anti-anxiety, hypnotic and sedative drugs Hemoglobin >10

Exclusion criteria:

History of coagulopathy Allergy to tranexamic acid Contraindication for spinal anesthesia and allergy to anesthetics and other drugs.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: 52

Randomization (investigator's opinion)

Randomized

Randomization description

For this purpose, the block randomization method of 50 blocks will be used. In this block, each cells contains the letters RA-LB (meaning the right hand of drug A and the left hand of drug B) or RB-LA (the right hand of drug B). and the left hand of drug A) which are randomly distributed. With the referral of each of the qualified patients, one of the houses is randomly selected and according to whether it is RA-LB or RB-LA. Right and left hand medicine type will be selected. And the selected cell will be crossed with a red pen in order not to be selected again. Codes A and B (normal saline or tranexamic acid) will be revealed at the end of the study and after the analysis.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Transgamic acid and normal saline will be drawn in syringes of the same color and shape with codes A and B by the operating room technician, and the codes will

remain secret with this person until the end of the research. Therefore, the patient, the surgeon who will measure and record the outcome of the study, and the statistical consultant will will be blind about the contents of the syringe used, and the study will be performed in a triple blind manner.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan Univercity of Medical Science

Street address

shahid fahmideh avenue

City

Hamadan

Province

Hamadan

Postal code

6517789971

Approval date

2023-07-01, 1402/04/10

Ethics committee reference number

IR.UMSHA.REC.1402.286

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

24 hours, 2 weeks, 1 month and 3 months post operation

Method of measurement

Clinical Examination

2

Description

Swelling
Timepoint
24 hours, 2 weeks, 1 month and 3 months post operation
Method of measurement
Clinical Examination

3

Description
Pain
Timepoint
24 hours, 2 weeks, 1 month and 3 months post operation
Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: After the completion of carpal tunnel syndrome surgery, two ampoules of tranexamic acid (2 grams) will be injected into the flexor sheet.
Category
Treatment - Drugs

2

Description
Control group: After the completion of carpal tunnel syndrome surgery, normal saline will be used inside the flexor sheet
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Hospital
Full name of responsible person
Dr. Bijan Heidari
Street address
Besat Hospital, Shahid Beheshti Blvd, Hamadan, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Abbas Moradi
Position
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Person responsible for updating data

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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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All data can be shared except for authors names

When the data will become available and for how long

From 2024 onwards it is permissible

To whom data/document is available

Clinical professionals and Researchers in all fields

Under which criteria data/document could be used

To develop research and science

From where data/document is obtainable

Correspond to the email address of the scientific responsible for the study

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

Send and receive email

Comments

No more information