

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of normal saline injection in medial nerve epithelium during carpal tunnel syndrome surgery

Protocol summary

Study aim

Effect of normal saline injection in median nerve epineurium during carpal tunnel syndrome release surgery

Design

A total of 100 patients who have the inclusion criteria will be randomly divided into intervention and control groups using a table of random numbers. The trial will be non-blinded, randomized, and in parallel groups.

Settings and conduct

In this clinical trial study, patients referred to Tabriz Imam Reza (AS) Hospital, will be candidates for surgery with the initial diagnosis of unilateral CTS (based on clinical examination and findings of electromyography and nerve conduction velocity) will be studied into two groups. The control group will undergo routine carpal tunnel release, and the intervention group will undergo normal saline injection into the endoneurium along with carpal tunnel release. Patients will be compared in terms of function and change of symptoms during discharge, a month after discharge, and 3,6 &12 months after surgery.

Participants/Inclusion and exclusion criteria

All patients with CTS who are candidates for surgery and are willing to participate in the study will enter the trial. Patients with bilateral symptoms, underlying disease, radiculopathy, and a history of surgery and fracture will not be included in the study.

Intervention groups

All patients are candidates for surgery and the surgical technique in all patients will be minimally invasive surgery. The common treatment will be performed in the control group. In the intervention group, after the release of the median nerve, a small amount of normal saline will be injected into the epineurium and the effect of this method will be compared and evaluated on follow-ups after surgery.

Main outcome variables

Patient performance status; Pain rate; The extent of

neurological symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210912052451N1**

Registration date: **2021-10-13, 1400/07/21**

Registration timing: **prospective**

Last update: **2021-10-13, 1400/07/21**

Update count: **0**

Registration date

2021-10-13, 1400/07/21

Registrant information

Name

Fardad Masoumi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6655 8219

Email address

masoumi.fardad@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2022-10-23, 1401/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of normal saline injection in medial nerve epithelium during carpal tunnel syndrome surgery

Public title
The effect of normal saline injection in medial nerve epithelium during carpal tunnel syndrome surgery

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Confirmation of CTS in the EMG-NCV in the initial examination candidate for surgery Participant's satisfaction
Exclusion criteria:
Bilateral CTS History of surgery and fracture in wrist Co-morbidities like diabetes or thyroid disease that exacerbates CTS Abnormalities and deformities of the wrist Radiculopathy Damage to other arteries such as radial and ulnar Elbow injuries and etc

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Due to the very high prevalence of the disease, patients will be randomly divided into two intervention groups (normal saline injection into endonorium) and the control group (routine surgery without saline injection) using a random number table. Depending on the sample size, which is 100, a 3-digit code will be considered for each sample. Randomization will then be applied using the Rand Company table.

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 Tabriz University of Medical Sciences

Street address
Shohada Hospital, Yaghchian, Golshahr Avenue, Tabriz, Iran

City
Tabriz

Province
East Azarbaijan

Postal code
5165665631

Approval date
2021-04-12, 1400/01/23

Ethics committee reference number
IR.TBZMED.REC.1400.059

Health conditions studied

1

Description of health condition studied

carpal tunnel syndrome

ICD-10 code

G56.00

ICD-10 code description

Carpal tunnel syndrome, unspecified upper limb

Primary outcomes

1

Description

Patient performance.

Timepoint

During discharge, one, 3, 6 and 12 months after surgery

Method of measurement

This variable will be measured based on clinical examinations and disabilities of the arm shoulder and hand score scale (DASH).

2

Description

Pain in hand.

Timepoint

During discharge, one, 3, 6 and 12 months after surgery

Method of measurement

This variable will be measured based on clinical examinations and visual analog scale.

3

Description

Neurological symptoms.

Timepoint

During discharge, one, 3, 6 and 12 months after surgery

Method of measurement

This variable will be measured based on clinical examinations.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, after the release of the median nerve with minimally invasive carpal tunnel release technique , 0.5 cc of normal saline(commonly used as a sterile 9 g of salt per litre (0.9%) solution) will be injected into the nerve endoneurium with an insulin syringe(31-29 gauge). Other surgical procedures, according to the usual technique, will be minimally invasive.

Category

Treatment - Surgery

2

Description

Control group: Routine minimally invasive surgery to median nerve release in the carpal tunnel will be performed.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz imam reza (as) hospital

Full name of responsible person

Mohammad Reza Moharrami

Street address

Imam reza (as) hospital, Golgasht street,Tabriz,Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Samiei

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Reza Moharrami

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Orthopedics

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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