

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

Comparison of the effectiveness of topical injection of vitamin B6 and steroids under ultrasound guide in carpal tunnel syndrome (CTS) on clinical and electrodiagnostic symptoms

Protocol summary

Study aim

Comparison of the effectiveness of topical injection of vitamin B6 and steroids under ultrasound guide in carpal tunnel syndrome (CTS) on clinical and electrodiagnostic symptoms of patients

Design

Clinical trial without control group, with parallel groups, No blinding, randomized, on 45 patients, for randomization, block method and random number table tool were used

Settings and conduct

Ultrasound guided injections are performed by longitudinal method on the median nerve in the wrist area and injections are performed at the exit of the carpal canal from the distal to the proximal. The study site is in the physical medicine and rehabilitation clinic of Baqiyatallah Hospital. This study is without blinding.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with final diagnosis of moderate carpal tunnel syndrome, no history of steroid injection into the carpal tunnel and history of surgery, no underlying diseases Exclusion criteria: patients with severe carpal tunnel syndrome, patients with neuropathy, patients with drug allergies

Intervention groups

1) Combination of topical injection of triamcinolone and lidocaine in two doses two weeks apart, each time containing 2 cc of drug containing 1 cc of triamcinolone 40 mg and 1 cc of 2% lidocaine 2) Combination of topical injection of vitamin B6 and lidocaine in two doses two weeks apart, each time 2 cc of drug containing 1 cc of vitamin B6 100 mg and 1 cc of lidocaine 2% 3) In the first case, 2 cc of drug including 1 cc of triamcinolone 40 mg and 1 cc of lidocaine 2% and two weeks later 1 cc of vitamin B6 100 mg topically in the wrist

Main outcome variables

Patient symptoms include anesthesia, pain, and

paresthesia based on the Visual analogue scale (VAS) ruler Electrophysiological findings based on Nerve Conduction Velocity (NCV)

General information

Reason for update

Acronym

CTS

IRCT registration information

IRCT registration number: **IRCT20210219050413N1**

Registration date: **2021-03-06, 1399/12/16**

Registration timing: **prospective**

Last update: **2021-03-06, 1399/12/16**

Update count: **0**

Registration date

2021-03-06, 1399/12/16

Registrant information

Name

Meysam Ehsani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8804 0060

Email address

dr.meysamehsani@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-21, 1400/01/01

Expected recruitment end date

2021-11-22, 1400/09/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of topical injection of vitamin B6 and steroids under ultrasound guide in carpal tunnel syndrome (CTS) on clinical and electrodiagnostic symptoms

Public title
Comparison of the effectiveness of topical injection of vitamin B6 and steroids in carpal tunnel syndrome(CTS)

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with a final diagnosis of moderate carpal tunnel syndrome with pain or paresthesia No history of steroid injection into the carpal tunnel No history of carpal tunnel surgery Absence of underlying diseases
Exclusion criteria:
Patients with severe carpal tunnel syndrome Severe hand dysfunction that requires surgical release of the median nerve Patients with neuropathy Upper limb fractures Burns in the upper limbs Patients undergoing hand surgery Patients with allergies to steroids, vitamin B6 and lidocaine Patients who do not have the necessary cooperation to follow up after the injection

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the randomization method is block, the individual randomization unit and the randomization tool using a table of random numbers

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 Baqiyatallah University of Medical Sciences

Street address

South Sheikh Baha'i St, Mulla Sadra St, Vanak Square, Tehran

City

Tehran

Province

Tehran

Postal code

1435915371

Approval date

2021-02-08, 1399/11/20

Ethics committee reference number

IR.BMSU.BAQ.REC.1399.051

Health conditions studied

1

Description of health condition studied

Carpal Tunnel Syndrome(CTS)

ICD-10 code

G56.0

ICD-10 code description

Carpal tunnel syndrome

Primary outcomes

1

Description

Clinical symptoms of patients (anesthesia)

Timepoint

Before treatment, three weeks and three months after treatment

Method of measurement

Using the Visual Analogue Scale ruler

2

Description

Clinical symptoms of patients (paresthesia)

Timepoint

Before treatment, three weeks and three months after treatment

Method of measurement

Using the Visual Analogue Scale ruler

3

Description

Clinical symptoms of patients (pain)

Timepoint

Before treatment, three weeks and three months after treatment

Method of measurement

Using the Visual Analogue Scale ruler

4**Description**

Electrodiagnostics

Timepoint

Before treatment, three weeks and three months after treatment

Method of measurement

Nerve Conduction Velocity

Secondary outcomes

empty

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

Intervention group: In the first group, the combination of topical injection of triamcinolone and lidocaine is injected twice in two weeks, each time 2 cc of drug including 1 cc of triamcinolone 40 mg and 1 cc of lidocaine 2% is injected

Category

Treatment - Drugs

2**Description**

Intervention group: In the second group, the combination of topical injection of vitamin B6 and lidocaine is given twice in two weeks, each time 2 cc of medicine including 1 cc of 100 mg of vitamin B6 and 1 cc of 2% lidocaine

Category

Treatment - Drugs

3**Description**

Intervention group: The third group first injects 2 cc of the drug, including 1 cc of triamcinolone 40 mg and 1 cc of lidocaine 2%, and two weeks later, 1 cc of vitamin B6 100 mg is injected topically into the wrist

Category

Treatment - Drugs

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

Physical Medicine and Rehabilitation Clinic of Baqiyatallah Hospital

Full name of responsible person

Meysam Ehsani

Street address

Baqiyatallah Hospital, South Sheikh Baha'i St, Mulla Sadra St, Vanak Square

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Email

dr.meysamehsani@bmsu.ac.ir

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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Ghulam Hossein Alishiri

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Baqiyatallah University of Medical Sciences, South Sheikh Baha'i St, Mulla Sadra St, Vanak Square

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ghalishiri@gmail.com

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

Yes

Title of funding source

Bagheiat-allah 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**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Meysam Ehsani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Meysam Ehsani

Position

Resident

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Position

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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