Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 onditudinalL 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)

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+98 21 8804 0060

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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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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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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