

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jun 2026

Evaluation of the effectiveness of Ultrasound-Guided Steroid Injection In one wrist in patients with bilateral carpal tunnel syndrome at opposite Injection side

Protocol summary

Study aim

Title: Results Survey of Ultrasound-Guided Steroid Injection In one wrist in patients with bilateral carpal tunnel syndrome at opposite Injection side

Design

Patients with CTS are injected with triamcinolone and lidocaine locally in one wrist (dominant hand)

Settings and conduct

physical medicine and rehabilitation clinic of Baqiyaallah

Participants/Inclusion and exclusion criteria

Inclusion criteria: 30-60 male or female patients with a final diagnosis of bilateral carpal tunnel syndrome with moderate intensity and pain or paresthesia in the hand. Exclusion criteria: 1- Patients with severe carpal tunnel syndrome or severe dysfunction of the hand that requires release of the median nerve through surgery. 2- Patients who suffer from neuropathy, radiculopathy and median nerve damage, as well as patients who suffer from brachial plexopathy, radial and ulnar neuropathy, fractures in the upper limb, burns in the upper limb and any type of nerve lesion in the upper limb. 3- Patients who undergo hand surgery. 4- Patients who are allergic to steroids and lidocaine. 5- Patients who do not cooperate to follow up after injection. 6- Patients who have a history of trauma or upper limb burns.

Intervention groups

30 Patients with Moderate CTS Bilateral diagnosed by EDX test, the combination of triamcinolone and lidocaine including 1 cc of triamcinolone 40 mg and 1 cc of 2% lidocaine is injected locally in one wrist (dominant hand) (the hand that has been injected), then For all patients, a medical wrist brace with a splint (Cock up) is prescribed for the dominant hand (the hand that has been injected) for one month.

Main outcome variables

carpal tunnel syndrome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230108057078N1**

Registration date: **2023-03-31, 1402/01/11**

Registration timing: **prospective**

Last update: **2023-03-31, 1402/01/11**

Update count: **0**

Registration date

2023-03-31, 1402/01/11

Registrant information

Name

Sattar Najafi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3344 3619

Email address

sattarn2a@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-04, 1402/01/15

Expected recruitment end date

2023-10-07, 1402/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of Ultrasound-Guided Steroid Injection In one wrist in patients with bilateral carpal tunnel syndrome at opposite Injection side

Public title

Evaluation of the effectiveness of Ultrasound-Guided Steroid Injection In one wrist in patients with bilateral carpal tunnel syndrome at opposite Injection side

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients With Bilateral Moderate Carpal Tunnel Syndrome Suffering From Hands Pain & Paresthesia No History Of Local Steroid Injection & Surgery No Underlying Disorders Such As Diabetes mellitus (DM), Thyroid Disorders & Rheumatoid Arthritis Within Range Of 30 To 60 Years Of Age Without Any Gender Limitation

Exclusion criteria:

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: **30**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

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

Sheikh Bahai - Mulla Sadra St. Vanak Square.Tehran

City

tehran

Province

Tehran

Postal code

Approval date

2022-07-16, 1401/04/25

Ethics committee reference number

IR.BMSU.BAQ.REC:1401.031

Health conditions studied

1

Description of health condition studied

Bilateral carpal tunnel syndrome

ICD-10 code

G56.0

ICD-10 code description

Carpal tunnel syndrome

Primary outcomes

1

Description

Bilateral carpal tunnel syndrome

Timepoint

before the start of the intervention and 30 days after local steroid injection

Method of measurement

EDX

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 30 patients with moderate bilateral CTS diagnosed by EDX test, the combination of triamcinolone and lidocaine including 1 cc of triamcinolone 40 mg and 1 cc of lidocaine 2% is injected locally in one wrist (dominant hand). The above-mentioned injections will be performed under ultrasound guide by hydrodissection of the Median nerve. Then, for one month, a medical wrist brace with a splint (Cock up) is prescribed for the dominant hand for all patients And then clinical symptoms (through the Boston questionnaire) and electrophysiological findings including NCV, SNAP Latency, CMAP Latency of the median nerve of the opposite hand are checked and recorded one month after the treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah Hospital, Tehran

Full name of responsible person

Seyyed Ebrahim Hashemi

Street address

Baqiyatullah-ul-Azam Hospital ,Mollasadra St, Vanak Square, Tehran

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Full name of responsible person

Satar Najafi

Position

Assistant professor

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

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Street address

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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

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Satar najafi

Position

Assistant professor

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Satar najafi

Position

Assistant professor

Latest degree

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Other areas of specialty/work

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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