

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Comparison of efficacy of ketorolac and triamcinolon acetone injection in treatment of carpal tunnel syndrome; A randomized clinical trial.

Protocol summary

Study aim

Comparison of the efficacy of triamcinolone and ketorolac injection for the treatment of carpal tunnel syndrome

Design

Randomized control trial with control parallel group, double blind

Settings and conduct

A randomized, double blind clinical trial with control group of this clinical trial was conducted on 50 patients with mild to moderate mild carpal tunnel syndrome referred to the educational centers of Shohadaee Tajrish and Modarres Hospital in Tehran. Patients were randomly divided into two groups: ketorolac Injection with Lidocaine and triamcinolone with Lidocaine injection

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 18-65 years with mild or moderate carpal tunnel syndrome; and had symptoms lasted for 3 months at least. The exclusion criteria: Pregnant women; severe carpal tunnel syndrome; underlying diseases like diabetes mellitus, thyroid dysfunction and rheumatoid arthritis; history of injection for carpal tunnel within last 6 months; presence of concurrent neuropathy or radiculopathy

Intervention groups

The first group received an injection of half a cc of lidocaine 2% with one cc of ketorolac under a single dose of 1 cc triamcinolon injection with 0/5 cc 2% lidocaine in a carpal tunnel

Main outcome variables

Visual analog scale for pain; Nerve conduction of median; Grip strength

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130523013442N29**

Registration date: **2019-09-13, 1398/06/22**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-13, 1398/06/22**

Update count: **0**

Registration date

2019-09-13, 1398/06/22

Registrant information

Name

Seyed Ahmad Raeissadat

Name of organization / entity

Modares Hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 2273 1112

Email address

a_raeissadat@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2020-01-21, 1398/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of ketorolac and triamcinolon acetone injection in treatment of carpal tunnel syndrome; A randomized clinical trial.

Public title

Comparison of efficacy of ketorolac and triamcinolon acetonide injection in treatment of carpal tunnel syndrome; A randomized clinical trial.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who suffer from mild or moderate carpal tunnel syndrome. Participants aged between 18 to 65 years Patients who had symptoms for at least 3 months

Exclusion criteria:

Women who were pregnant Participants who had severe carpal tunnel syndrome Patients who had past history of disorders like diabetes mellitus, thyroid dysfunction and rheumatoid arthritis Patients who had history of local injection of steroids within last 3 months Patients who had concomitant underlying neuropathy or radiculopathy

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

More than 1 sample in each individual

Number of samples in each individual: **2**

Patients with bilateral carpal tunnel syndrome will gain from different injection approaches

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, simple individual randomization method in the form of sealed envelopes, will be used

Blinding (investigator's opinion)

Double blinded

Blinding description

The participant and outcome assessor will be blinded about the patients` group

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committe of Shahid Beheshti University of

Medical Sciences

Street address

No. 1983969411, Shahid Beheshti University of Medical sciences, Shahid Arabi Street, Yaman Street, Shahid Chamran Highway, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1983969411

Approval date

2018-08-08, 1397/05/17

Ethics committee reference number

IR.SBMU.MSP.REC.1397.397

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

pain

Timepoint

Before intervention and 10 weeks after injection

Method of measurement

Visual Analogue Scale

2

Description

function

Timepoint

Before intervention 1 and 3 months after injection

Method of measurement

Boston questionnaire

3

Description

Sensory and motor nerve conduction

Timepoint

Before intervention 1 and 3 months after injection

Method of measurement

Nerve electrophysiologic study

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Local injection of 1cc ketorolac with 0/5 cc lidocaine 2%

Category

Treatment - Drugs

2

Description

Control group: Local injection of 1cc triamcinolone with 0/5 cc lidocaine 2%

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Modarres Hospital

Full name of responsible person

maryam esmaelzade

Street address

No. 1998734383, Shahid Modarres Hospital, Kaj square, Saadat Abad

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2

Recruitment center

Name of recruitment center

Shohada Tajrish Hospital

Full name of responsible person

maryam esmaelzade

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Shahrdari street, Tajrish square, Shohada Tajrish Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

maryam esmaelzade

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

maryam esmaelzade

Position

Resident in Physical Medicine and Rehabilitation

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

Seyed Ahmad Raeissadat

Position

دانشیار

Latest degree

Specialist

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

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Position

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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