

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of clinical effectiveness of ketorolac and Triamcinolone injection in patients with moderate to severe carpal tunnel syndrome

Protocol summary

Study aim

Determination and Comparison of clinical effectiveness of ketorolac and triamcinolone injection in patients with moderate carpal tunnel syndrome patients

Design

Clinical trials without control group, with parallel groups, double blind, randomized, Sample size 45 person, 60 wrists

Settings and conduct

The sample included patients referred to the Physical Medicine Clinic of Imam Reza Hospital, Tabriz, Iran. The diagnosis of carpal tunnel syndrome with electrodiagnosis was given to them. All patients referred to the Imam Reza and Madani Hospital in Tabriz, who are referred to the Medical Physics Department of the Carpal Tunnel Syndrome Diagnosis, are measured by the hand dynamometer. Boston's carpal tunnel questionnaire (BCTQ) is also used for evaluation. The severity of carpal tunnel syndrome will be performed. In this study patients will be divided into two groups and will be injected for a triamcinolone group and for another group of ketorolacs by an experienced physician and rehabilitation specialist. Then, a three-month Boston functional questionnaire will be provided to the patients and the information will be compared. After the patient's illness and explanation, the patient's informed consent is divided into two groups, and the attendant's caregivers perform the necessary services for the patients according to the order of the investigator.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having moderate carpal tunnel syndrome criteria Exclusion criteria: atrophy of the thenar muscle and no desire for surgery

Intervention groups

Intervention group 1: Ketorolac recipient group
Intervention group 2: Triamcinolone recipient group

Main outcome variables

Changes in Boston Questionnaire; Changes in latency and amplitude of Median Nerve Sensory and Motor Action Potential; Wrist Strength Changes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190326043118N1**

Registration date: **2019-09-17, 1398/06/26**

Registration timing: **retrospective**

Last update: **2019-09-17, 1398/06/26**

Update count: **0**

Registration date

2019-09-17, 1398/06/26

Registrant information

Name

amirreza ghanbari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3542 2706

Email address

amirrezaghanbari1372@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-14, 1398/01/25

Expected recruitment end date

2019-04-25, 1398/02/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of clinical effectiveness of ketorolac and Triamcinolone injection in patients with moderate to severe carpal tunnel syndrome

Public title

Comparison of clinical effectiveness of ketorolac and Triamcinolone injection in patients with moderate to severe carpal tunnel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Proof of Carpal Tunnel Syndrome Moderate with STEVENS Electrodiogenesis Criteria CMAP latency>4.2msec SNAP latency>3.0msec SNAP latency>3.0msec+low amplitude SNAP NCV across wrist<40m/sec CMAP Amplitude <4mv with SNAPs amplitude <12uv without symptoms of degeneration (fib / psw) in tension in Nidal EMG

Exclusion criteria:

Symptoms of atrophy of the tenar Contraindication of corticosteroid injection such as corticosteroid hypersensitivity and injection site infection Treatment of carpal tunnel syndrome with surgery or corticosteroid injection over the past 6 months Traumatic or neoplastic origin of symptoms No consent for injection Symptoms of denervation in electromyography suggestive of severe axonal injury Symptoms of active cervical radiculopathy in electromyography or cervical disc protrusion in MRI

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

- Participant

Sample size

Target sample size: **45**

More than 1 sample in each individual

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

Patients who were involved bilaterally received both wrists and And only one hand was involved in patients with one wrist involved.Finally, 45 patients and 60 wrists were studied

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

After randomization and informed patient satisfaction, each patient is randomly assigned a number that is paired for triamcinolone injection and individual for ketorolac injection.Clinical care according to numbers will inject one of the drugs for the patient.

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

Central Office of the University of Medical Sciences,Golgasteh Street , Azadi Avenue , TABRIZ

City

tabriz

Province

East Azarbaijan

Postal code

5166616471

Approval date

2019-08-21, 1398/05/30

Ethics committee reference number

IR.TBZMED.REC.1398.564

Health conditions studied

1

Description of health condition studied

CARPAL TUNNEL SYNDROME

ICD-10 code

G56.0

ICD-10 code description

Carpal tunnel syndrome

Primary outcomes

1

Description

Total score of Carpal Tunnel Syndrome Questionnaire Boston To measure severity of symptoms and dysfunction

Timepoint

Before intervention and 3 months later

Method of measurement

boston carpal tunnel questionnaire

Secondary outcomes

1

Description

hand power

Timepoint

Before intervention and 3 months later

Method of measurement

hand dynamometer

Intervention groups

1

Description

Intervention group 1: Ketorolac group 30 mg Alborz Daru group injected under ultrasound guide ide

Category

Treatment - Drugs

2

Description

Intervention group2: Triamcinolone group 40 mg manufactured by Iran hormone injected under ultrasound guide

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Emam Reza

Full name of responsible person

Alireza Pishghahi

Street address

Department of Physical Medicine and Rehabilitation, Imam Reza Hospital, University Square, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5138636762

Phone

+98 41 3542 2706

Email

Alirezapishgahi1364@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Samii

Street address

Department of Physical Medicine and Rehabilitation, Imam Reza Hospital, Golshat Street, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5138636762

Phone

+98 41 3335 7310

Email

Samiei.moh@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, 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

Amirreza Ghanbari

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Department of Physical Medicine and Rehabilitation, Imam Reza Hospital, Golshat Street, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5138636762

Phone

+98 41 3542 2706

Email

amirrezaghanbari1372@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Alireza Pishghahi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

Street address

Department of Physical Medicine and
Rehabilitation, Imam Reza Hospital, Golshat Street,
Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5138636762

Phone

+98 41 3336 1928

Email

Alirezapishgahi1364@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Alireza Pishgahi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

Street address

Department of Physical Medicine and

Rehabilitation, Imam Reza Hospital, Golshat Street,
Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5138636762

Phone

+98 41 3336 1928

Email

Alirezapishgahi1364@gmail.com

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