

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effect of Ultrasound-Guided Local Steroid Injection with Hydro-dissection on Symptom Severity, Ultrasound and Nerve Conduction Study of Median Nerve in Carpal Tunnel Syndrome Patients: A Randomized Clinical Trial

Protocol summary

Summary

This study designed for comparison therapeutic effect of ultrasound guided corticosteroid injection with Hydrodissection, injection without Hydrodissection and wrist splinting on carpal tunnel syndrome. Mild to moderate carpal tunnel syndrome patients referred to Baqiyatallah University of Medical Sciences polyclinic and University of Social Welfare and Rehabilitation Sciences affiliated clinics will enroll. Patients with severe carpal tunnel syndrome and severe dysfunction needing surgical releasing and Patients with history of other therapeutic methods will exclude. One hundred fifty carpal tunnel syndrome patients will randomize to five groups by a computed-generalized randomization list: Injection of 80 mg triamcinolone with 1 ml lidocaine 2% by Hydrodissection method in group one; injection of 40 mg triamcinolone with 1 ml distilled water and 1 ml lidocaine 2% by Hydrodissection method in group two; injection of 2 ml distilled water and 1 ml lidocaine 2% by Hydrodissection method in group three; injection of 40 mg triamcinolone without Hydrodissection method in group four; and wrist splinting in group five. In groups one to four, injections will perform 3 times with 2 week intervals. Efficacy of injections on hand performance, nerve conduction and ultrasound study of median nerve and symptoms severity will evaluate before each injection. Group five patients also followed 6 weeks as control. Collected data will compare in these groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014020416485N1**

Registration date: **2014-05-04, 1393/02/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-05-04, 1393/02/14

Registrant information

Name

Reza Salman Roghani

Name of organization / entity

Department of Clinical Sciences, University of Social Welfare and Rehabilitation, Tehran, Iran

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Deputy of Research, University of Social Welfare and Rehabilitation Sciences

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2014-02-20, 1392/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Ultrasound-Guided Local Steroid Injection with Hydro-dissection on Symptom Severity, Ultrasound and Nerve Conduction Study of Median Nerve in Carpal Tunnel Syndrome Patients: A Randomized Clinical Trial

Public title

Therapeutic Effect of Ultrasound-Guided Local Steroid Injection with Hydro-dissection in Carpal Tunnel Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Mild to moderate carpal tunnel syndrome patients with no history of surgical and local steroid injection, without age and gender limitation. Exclusion criteria: Patients with severe carpal tunnel syndrome and severe dysfunction that needs surgical median nerve releasing; patients with history of other therapeutic approaches; history of allergy against steroids or triamcinolone; steroid contraindications; history of cardiac arrhythmia; diabetes mellitus; hand surgeries in past 3 months; Arthritis rheumatoid; cervical radiculopathy; thyroid dysfunctions

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Baqiyatallah University of Medical Sciences Ethics Committee

Street address

Baqiyatallah University of Medical Sciences, Nosrati alley, Sheikh Bahaei St, Mollasadra St, Vanak Sq, Tehran, I.R.Iran.

City

Tehran

Postal code**Approval date**

2014-01-05, 1392/10/15

Ethics committee reference number

34-13

Health conditions studied**1****Description of health condition studied**

Carpal tunnel syndrome

ICD-10 code

G56.0

ICD-10 code description

upper limb mononeuropathy

Primary outcomes**1****Description**

Boston's Questionnaire score

Timepoint

Every two weeks

Method of measurement

Questionnaire score

2**Description**

Median nerve ultrasound study

Timepoint

Every two weeks

Method of measurement

Diameter and cross section of median nerve

3**Description**

Median nerve conduction study

Timepoint

Every two weeks

Method of measurement

Motor and sensory latency of median nerve

4**Description**

Pain Score

Timepoint

Every two weeks

Method of measurement

visual analogue score

Secondary outcomes

empty

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

Injection of 80 mg triamcinolone with 1 ml lidocaine 2% by Hydrodissection method

Category

Treatment - Other

2**Description**

Injection of 40 mg triamcinolone with 1 ml distilled water and 1 ml lidocaine 2% by Hydrodissection method

Category

Treatment - Other

3**Description**

Injection of 2 ml distilled water and 1 ml lidocaine 2% by Hydrodissection method

Category

Treatment - Other

4**Description**

Injection of 40 mg triamcinolone without Hydrodissection method

Category

Treatment - Other

5**Description**

Wrist splinting for 6 weeks

Category

Rehabilitation

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

University of Social Welfare and Rehabilitation Sciences (USWR) affiliated Clinics

Full name of responsible person

Reza Salman Roghani

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University of Social Welfare and Rehabilitation Sciences (USWR), Daneshjoo BLVD, Evin, Tehran, Iran.

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2**Recruitment center****Name of recruitment center**

Baqiyatallah University of Medical Sciences Policlinic

Full name of responsible person

Hamidreza Karimi Sari

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

University of Social Welfare and Rehabilitation Sciences (USWR), Deputy of Research

Full name of responsible person

Reza Salman Roghani

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University of Social Welfare and Rehabilitation Sciences (USWR), Daneshjoo BLVD, Evin, Tehran, Iran.

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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

University of Social Welfare and Rehabilitation Sciences (USWR), Deputy of Research

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

University of Social Welfare and Rehabilitation Sciences (USWR), Aging Research Center

Full name of responsible person

Hamidreza Karimi Sari

Position

General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty