Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Oct 2026

Study of the effects of local Progesterone injection versus Corticosteroid injection in patients with mild and moderate Carpal Tunnel Syndrome in Physical Medicine and Rehabilitation clinic of Modarres and shohadaie Tajrish Hospitasls from 2012 to 2013

Protocol summary

Summary

This single blind Randomized Clinical Trial was designed to compare the effects of Corticosteroid versus Progesterone injection in patients with idiopathic mild to moderate Carpal Tunnel Syndrome. A total of sixty patients will be randomly assigned into 2 groups,group A and group B.Group A was treated with a single injection of 1 ml of triamcinolon and group B with 1 ml 17 alpha hydroxiprogesterone . Both groups used prefabricated hand wrist splint for CTS for 8 weeks. Pain visual analog scale (VAS), (BQ-SYMPT) Bostone/Levine symptom severity scale and Bostone/Levine functional status scale(BQ-FUNC) and EDX studys will be assessed before intervention, 10 weeks and 6 months after the intervention

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013101313442N4**
Registration date: **2013-11-01, 1392/08/10**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-11-01, 1392/08/10

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

Physical Medicine and Rehabilitation Departement of Shahid Beheshti University of Medical Sience.

Expected recruitment start date

2012-12-21, 1391/10/01

Expected recruitment end date

2013-10-02, 1392/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effects of local Progesterone injection versus Corticosteroid injection in patients with mild and moderate Carpal Tunnel Syndrome in Physical Medicine and Rehabilitation clinic of Modarres and shohadaie Tajrish Hospitasls from 2012 to 2013

Public title

Effects of local Progesterone injection versus Corticosteroid injection in patients with Carpal Tunnel Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: patient with mild and moderate CTS confirmed by the presence of 1 or more of the following

standard electrophysiological criteria:1- prolonged distal motor latency (DML) (abnormal ≥4.2 ms)of Median nerve and 2) prolonged antidromic distal sensory latency (DSL) to the third digit (abnormal >3.6 ms; age between 20 to 65 years old. Exclusion criteria:Pregnancy; Severe degree CTS; Background metabolic diseases such as: Diabetes mellitus; Hypothyroidism; Rheumatoid arthritis; Previous history of Corticosteroid injection in Carpal Tunnel; Severe atrophy of Thener muscles; cervical radiculopathy or significant polyneuropathy; Unwillingness to participate in the present study; patient younger than 20 or older than 65 years old.

Age

From **20 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committe of faculty of Medicine,Shahid Beheshti University of Medical siences

Street address

Shahid Beheshti University of Medical siences, next to Taleghani Hospital, yaman street, Chamran Highway

City

Tehran

Postal code

Approval date

2012-12-09, 1391/09/19

Ethics committee reference number

400/8770

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

Pain

Timepoint

0,10 weeks, 6 months

Method of measurement

Visual Analog Scale, that is from 0-10 and zero (0) means that you did not have any pain and ten (10) means that you had the worst pain imaginable

2

Description

Functional Status

Timepoint

0, 6weeks, 6months

Method of measurement

Bostone/levine Functional Status Scale Questionnare

3

Description

Symptome Severity(pain and paresthesia)

Timepoint

0,10weeks, 6months

Method of measurement

Bostone/levine Symptome Severity Scale Questionnare

4

Description

Distal Sensory Peak Latency(SNAP) of median nerve

Timepoint

0,10weeks, 6months

Method of measurement

EDX Indexes

5

Description

Distal Motor Onset Latency(CMAP) of median nerve

Timepoint

0,10weeks, 6months

Method of measurement

EDX indexes

Secondary outcomes

1

Description

Patient Satisfication after trearment

Timepoint

0,10weeks, 6months

Method of measurement

Patient statement

Intervention groups

1

Description

Single injection of 1 ml of Triamcinolon with 2cc syringe and Prefabricated hand wrist splint for CTS for 8 weeks

Category

Treatment - Drugs

2

Description

Single injection of 1 ml 17 Alpha Hydroxiprogesterone with 2cc syringe and Prefabricated hand wrist splint for CTS for 8 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Modarres Hospital

Full name of responsible person

Shadi Shahraeeni

Street address

Shahid Modarres Hospital, Kaj square, Saadat Abad street

City

Tehran

2

Recruitment center

Name of recruitment center

Shohada Tajrish Hospital

Full name of responsible person

Shadi Shahraeeni

Street address

Shahrdari street, Tajrish square, Shohada Tajrish Hospital

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Physical Medicine and Rehabilitation Departement of Shahid Beheshti University of Medical Science

Full name of responsible person

Vice chancellor for research, Seyed Ahmad Raeissadat

Street address

Physical Medicine and Rehabilitation Departement, Shahid Modarres Hospital, Kaj square, Saadat abad

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Physical Medicine and Rehabilitation Departement of Shahid Beheshti University of Medical Science

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

Modarres Hospital

Full name of responsible person

Shadi Shahraeeni

Position

Physical Medicine and Rehabilitation resident

Other areas of specialty/work

Street address

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Web page address

Person responsible for scientific inquiries

Contact

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Shahid Modarres Hospital

Full name of responsible person

Seyed Ahmad Raeissadat

Position

Assistant Professor

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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