Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effects of single Platelet-Rich Plasma local injection on pain, symptom severity, functional state and electrodiagnostic findings in women with mild and moderate Carpal Tunnel Syndrome, A clinical trial

Protocol summary

Summary

Objectives: This study is designed to indicate the short term effects of Platelet-Rich Plasma (PRP) injection on VAS score, symptom severity and functional status based on Boston questionnaire and electrodiagnostic findings of women with idiopathic mild and moderate Carpal Tunnel Syndrome (CTS). Study Design: This study is a non-blind randomized clinical trial. Randomization will be done by computer generated random numbers. Setting and conduct:A total of 41 patients will be randomly assigned to two groups of control, only using a wrist splint, and PRP that received wrist splints along with a single local injection of in the carpal tunnel. Participants: Participants are women referring to the physical medicine and rehabilitation clinics at Shahid Modarres Hospital during 2016 with a diagnosis of mild and moderate idiopathic CTS aged 20 to 65 without any comorbidities such as thyroid disease or diabetes mellitus. Interventions: Both groups will use the same prefabricated hand wrist splint for CTS along with PRP group will be treated with a single injection of 1 ml of PRP plus 0.5 ml lidocaine 1% in the carpal tunnel. outcome measures: At the beginning and 10 weeks after the intervention, outcome measures which are Pain visual analog scale (VAS), (BQ-SYMPT) Boston/Levine symptom severity scale and Boston/Levine functional status scale (BQ-FUNC), median nerve sensory peak latency and median nerve will be assessed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017041513442N13**
Registration date: **2017-06-19, 1396/03/29**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-06-19, 1396/03/29

Registrant information

Name
Seyed Ahmad Raeissadat
Name of organization / entity
Modares Hospital
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Recruitment status

Recruitment complete

Funding source

Physical Medicine and Rehabilitation Department

Expected recruitment start date

2017-02-22, 1395/12/04

Expected recruitment end date

2017-04-30, 1396/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of single Platelet-Rich Plasma local injection on pain, symptom severity, functional state and electrodiagnostic findings in women with mild and moderate Carpal Tunnel Syndrome, A clinical trial

Public title

Effects of Platelet-Rich Plasma local injection in

treatment of women with mild and moderate carpal tunnel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patient with mild and moderate CTS confirmed by the presence of one or more of the following standard electrophysiological criteria: 1- prolonged distal motor latency (DML) (abnormal response is more than 4.2 millisecond) of Median nerve and 2- prolonged antidromic distal sensory latency (DSL) to the third digit (abnormal response is more than 3.6 millisecond); Exclusion criteria: Pregnancy; Severe degree CTS; Background metabolic diseases such as: diabetes mellitus; hypothyroidism; rheumatoid arthritis; Previous history of corticosteroid injection in Carpal Tunnel Syndrome; Severe atrophy of thenar muscles; cervical radiculopathy or significant polyneuropathy; Unwillingness to participate in the present study; patient younger than 20 or older than 65 years old; history or presence of cancer or malignant disorders; presence of immunosuppressive, autoimmune and platelet disorders; treatment with anticoagulant and anti-platelet medications 10 days before injection; use of NSAIDs 2 days before injection; use of systemic corticosteroids 2 weeks before PRP injections; hemoglobin measures of less than 12 g/dl and platelet counts of less than 150,000 per micro liter

Age

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

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **41**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

randomization via computer generated random numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Of Shahid Beheshti University Of Medical Sciences

Street address

Shahid Beheshti University of Medical Siences, Next to Taleghani Hospital, Yaman Street, Chamran Highway Tehran Iran, Islamic Republic Of Iran

City

Tehran

Postal code

Approval date

2016-11-05, 1395/08/15

Ethics committee reference number

IR.SBMU.MSP.REC.1395.382

Health conditions studied

1

Description of health condition studied

carpal tunnel syndrome

ICD-10 code

G56.0

ICD-10 code description

Mononeuropathies of upper limb

Primary outcomes

1

Description

pain

Timepoint

at the beginning and after 10 weeks of injection or 10 weeks after starting using splint

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

Secondary outcomes

1

Description

median CMAP distal latency

Timepoint

at the beginning and after 10 weeks of injection or 10 weeks after starting using splint

Method of measurement

Electrodiagnostic study

2

Description

symptom severity

Timepoint

at the beginning and after 10 weeks of injection or 10 weeks after starting using splint

Method of measurement

Boston/Levine symptome severity scale

3

Description
median SNAP peak latency
Timepoint
at the beginning and after 10 weeks of injection or 10 weeks after starting using splint
Method of measurement
Electrodiagnostic study

4

Description
Functional Status
Timepoint
at the beginning and after 10 weeks of injection or 10 weeks after starting using splint
Method of measurement
boston questionaire

Intervention groups

1

Description
Single injection of 1 ml of PRP with 0.5 ml lidocain 1% in carpal tunnel and prefabricated hand wrist splint in neutral position for CTS
Category
Treatment - Drugs

2

Description
Prefabricated hand wrist splint in neutral position for CTS
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Modarres Hospital, Shahid Beheshti Univeraity of Medical Sciences
Full name of responsible person
Seyed Ahmad Raeissadat
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Shahid Modarres Hospital, Kaj Square, Saadat Abad street, Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research,Shahid Beheshti University of Medical Sciences
Full name of responsible person
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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
Vice chancellor for research,Shahid Beheshti University of Medical Sciences
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
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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