

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 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

###### 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 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 the 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 Sciences, 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 questionnaire

## **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

##### **Street address**

Shahid Modarres Hospital, Kaj Square, Saadat Abad street, Tehran

##### **City**

Tehran

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

#### **Full name of responsible person**

Seyed Ahmad Raeissadat

#### **Street address**

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

#### **City**

Tehran

#### **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**

##### **Name of organization / entity**

Shahid Beheshti Univeraity of Medical Sciences

##### **Full name of responsible person**

Leila Bagherzadeh

##### **Position**

Resident in physical medicine and rehabilitation

##### **Other areas of specialty/work**

##### **Street address**

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## **Person responsible for scientific inquiries**

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##### **Position**

Associate Professor

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**Position**

Resident in physical medicine and rehabilitation

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**Web page address**

**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*