

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### The effect of platelet rich plasma (PRP) on pain and function in patients with lateral ankle sprain after modified Brostrom surgery, a randomized clinical trial

#### Protocol summary

##### Study aim

The effect of platelet rich plasma on pain and function in patients with lateral ankle sprain after modified Brostrom surgery

##### Design

A randomized, single-blinded, clinical trial with a control group on 20 patients. Randomization will be performed using an online block randomization tool ([www.sealedenvelope.com](http://www.sealedenvelope.com)).

##### Settings and conduct

Initially, we will record the following items for patients who meet the inclusion criteria: Height, weight, Body mass index, pain by visual analog scale (VAS), ankle function by American Orthopedic Foot and Ankle Score (AOFAS), and ankle total range of motion (total ROM). Then, Brostrom surgery will be performed by an orthopedic surgeon for both groups at Akhtar Hospital in Tehran. One week postoperatively, along with the routine treatment, the intervention group will be injected with 5 cc of PRP at the ligament surgery site under ultrasound guide. two and six weeks postoperatively, 5 cc of PRP will be injected into the tibiotalar joint under ultrasound guide for the intervention group. The control group also receives only routine treatment after surgery. VAS, AOFAS, and total ROM will be recorded at the first visit, three and six months after surgery for both groups.

##### Participants/Inclusion and exclusion criteria

Patients with lateral ankle sprain grade 3; No history of ankle surgery, ankle osteoarthritis, inflammatory diseases, and confounders in the study results, and no ankle deformities.

##### Intervention groups

One, two, and six weeks after surgery, a certain volume of peripheral blood will be taken from each patient in the intervention group and will be converted into PRP by a trained person using a standard kit. The intervention group receives routine treatment along with PRP. The

control group received only routine treatment.

##### Main outcome variables

Ankle pain by VAS; ankle function by AOFAS and total ROM

#### General information

##### Reason for update

Randomization changed from pseudorandomized to randomized. Participants were not blinded, but the outcome assessor, researchers, and data analysts were blinded. The control group did not receive a placebo injection. The number of platelet-rich plasma injections increased to 3 for the intervention group. Lidocaine was not added to the platelet-rich plasma solution. The study changed from double-blinded to single-blinded. In the variables section, the FAAM variable was deleted. patients Follow-up was performed 3 and 6 months after surgery.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200307046714N1**  
Registration date: **2022-01-15, 1400/10/25**  
Registration timing: **prospective**

Last update: **2022-09-08, 1401/06/17**

Update count: **2**

##### Registration date

2022-01-15, 1400/10/25

##### Registrant information

##### Name

Hooshmand Zarei

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4409 8132

##### Email address

hooshmand.z1994@gmail.com

**Recruitment status**  
**Recruitment complete**  
**Funding source**

**Expected recruitment start date**  
2022-01-20, 1400/10/30

**Expected recruitment end date**  
2022-03-20, 1400/12/29

**Actual recruitment start date**  
empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
The effect of platelet rich plasma (PRP) on pain and function in patients with lateral ankle sprain after modified Brostrom surgery, a randomized clinical trial

**Public title**  
The effect of platelet rich plasma in lateral ankle sprain

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**

Age over 18 years Grade 3 (severe) ligament injury based on clinical and imaging criteria and no ankle fracture

**Exclusion criteria:**  
Pregnancy Breastfeeding Those who intend to become pregnant History of peripheral vascular diseases Rheumatoid Arthritis Knee or ankle osteoarthritis Ankylosing spondylitis Foot deformities Diabetes Neurological disorders Psychiatric disorders History of surgery and active infection at the site of injury

**Age**  
From **18 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **20**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Randomization was performed using an online block randomization tool (www.sealedenvelope.com), with a variable block size of 2 or 4, and stratified based on age ( $\geq 40$  or  $< 40$  years).

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**

Evaluation of the outcomes will be performed by a foot and ankle surgeon who is unaware of patients' randomization. The physiotherapist who will prescribe the physiotherapy program and the researchers who will perform the statistical analysis will also be blinded to the randomization.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

**Secondary ids**  
empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Shahid Beheshti University of Medical Sciences

**Street address**

Next to Ayatollah Taleghani Hospital, Shahid Arabi St., Yemen St., Shahid Chamran Highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717434

**Approval date**

2021-02-21, 1399/12/03

**Ethics committee reference number**

IR.SBMU.RETECH.REC.1399.1264

**Health conditions studied**

1

**Description of health condition studied**

lateral ankle sprain

**ICD-10 code**

S93.40

**ICD-10 code description**

Sprain of unspecified ligament of ankle

**Primary outcomes**

1

**Description**

Determination of ankle pain

**Timepoint**

The first visit, three months after surgery, six months after surgery

**Method of measurement**

Questionnaire (VAS)

## 2

### **Description**

Determination of ankle function

### **Timepoint**

The first visit, three months after surgery, six months after surgery

### **Method of measurement**

Questionnaire (AOFAS)

## 3

### **Description**

Determine the ankle total range of motion (total ROM)

### **Timepoint**

The first visit, three months after surgery, six months after surgery

### **Method of measurement**

Manual joiniometry

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: In this group of patients, 50 ccs of peripheral blood will be taken from each patient by a 50cc syringe in the first, second, and sixth weeks after surgery, then centrifuged and converted to 5 ccs PRP. The first PRP solution will be injected into the site of lateral ligament surgery under ultrasound guide by a physician. The second and third injections will be also injected into the tibiotalar joint by the same physician under ultrasound guide.

#### **Category**

Treatment - Other

### 2

#### **Description**

Control group: This group receives only routine treatment after surgery.

#### **Category**

Treatment - Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Akhtar Hospital

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

Hooshmand Zarei, MD

##### **Street address**

Sharifi Manesh St., Poule Roomi Ave, Shariati St.

##### **City**

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##### **Province**

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##### **Postal code**

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##### **Phone**

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## **Sponsors / Funding sources**

### 1

#### **Sponsor**

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

Shahid Beheshti University of Medical Sciences

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

Afshin Zarghi, Ph.D

##### **Street address**

Vice-Chancellor in Research Affairs, 5th Floor, Bldg No.2 Shahid Beheshti University of medical sciences Arabi Ave, Daneshjoo Blvd, Velenjak

##### **City**

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##### **Email**

Mpajouhesh@sbmu.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

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

Hooshmand Zarei, MD

##### **Position**

General Practitioner

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

Unit 6, No.19, 3th St., North Shaghayegh Blvd.,  
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**Person responsible for scientific inquiries**

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**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Amir Sabbaghzadeh Irani, MD

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Orthopedics

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Hooshmand Zarei, MD

**Position**

General Practitioner

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

Unit 6, No.19, 3th St., North Shaghayegh Blvd.,  
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**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