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).

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)

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+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 (≥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
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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
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Sharifi Manesh St., Poule Roomi Ave, Shariati St.
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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
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Vice-Chancellor in Research Affairs, 5th Floor, Bldg No.2 Shahid Beheshti University of medical sciences Arabi Ave, Daneshjoo Blvd, Velenjak
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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
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

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Person responsible for scientific inquiries

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Person responsible for updating data

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Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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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