

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jul 2026

### Effects of Platelet Rich Plasma in Treatment of patients with Long Bones Non-unions: A Randomized Double-Blind Clinical Trial

#### Protocol summary

##### Summary

The aim of this study is to determine the effects of plasma rich platelet (PRP) on healing rate of long bones non-union. A total number of 70 adult (>18 years) patients suffering from long bones (Femur, Tibia, Fibula, Humerus, Ulna, Radius) with duration of more than 6 months will be randomly assigned to receive 5mL PRP (n=35) or 5mL placebo (n=35) in the site of fracture after intramedullary nailing or open reduction and internal fixation (ORIF). Those with infectious non-union, vascular injuries, malignancies, skin defects, metabolic bone disorders and platelet count <100,000/ $\mu$ L would be excluded. Patients would be followed each 45 days till 9 months and would be evaluated both clinically and radiologically. The healing rate, failure rate, incidence of infection, mal-union and limb shortening would be recorded and compared between groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201208262445N1**

Registration date: **2012-09-23, 1391/07/02**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-09-23, 1391/07/02

##### Registrant information

###### Name

Fariborz Ghaffarpasand

###### Name of organization / entity

Shiraz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3647 4259

##### Email address

ghafarf@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Trauma Research Center - Shiraz University of Medical Sciences

##### Expected recruitment start date

2011-05-01, 1390/02/11

##### Expected recruitment end date

2012-10-21, 1391/07/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effects of Platelet Rich Plasma in Treatment of patients with Long Bones Non-unions: A Randomized Double-Blind Clinical Trial

##### Public title

Effects of Platelet Rich Plasma in Treatment of patients with Long Bones Non-unions

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Age >18 years; long bone non-unions (Femur, Tibia, Fibula, Humerus, Ulna, Radius) with duration of more than 6 months Exclusion criteria: Age <18 years; infectious non-unions; vascular injuries; large skin defects of fracture site; musculoskeletal disorders; malignancies; pathological fractures (tumors, metabolic osteopenia); active autoimmune disorders; large bone defects; platelet count <100,000 per micro-liter; treatment with growth factors within the previous

years; treatment with steroids and NSAIDs during the previous year

#### Age

From **18 years** old to **45 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **70**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of AJA University of Medical Sciences

##### Street address

AJA University of Medical Sciences, West Fatemi Street, Etemadzadeh Street, Tehran

##### City

Tehran

##### Postal code

#### Approval date

2011-10-30, 1390/08/08

#### Ethics committee reference number

4920/51

## Health conditions studied

### 1

#### Description of health condition studied

Nonunion of fracture

#### ICD-10 code

M84.1

#### ICD-10 code description

Nonunion of fracture [pseudarthrosis]

## Primary outcomes

### 1

#### Description

Clinical cure rate

#### Timepoint

Postoperative days 45, 90, 135, 180, 225, 270

#### Method of measurement

Physical examination

### 2

#### Description

Radiological cure rate

#### Timepoint

Postoperative days 45, 90, 135, 180, 225, 270

#### Method of measurement

Anteroposterio and lateral radiography views

## Secondary outcomes

### 1

#### Description

Incidence of infection

#### Timepoint

Postoperative days 45, 90, 135, 180, 225, 270

#### Method of measurement

Bacterial culture

### 2

#### Description

Muscular trophism

#### Timepoint

Postoperative days 45, 90, 135, 180, 225, 270

#### Method of measurement

Physcial examination

### 3

#### Description

Incedence of mal-union

#### Timepoint

Postoperative days 45, 90, 135, 180, 225, 270

#### Method of measurement

Anteroposterio and lateral radiography views

### 4

#### Description

Pain severity

#### Timepoint

Postoperative days 45, 90, 135, 180, 225, 270

#### Method of measurement

Visual Analogue Scale (VAS)

## Intervention groups

### 1

#### Description

Injection of 5 milliliters of plasma rich platelet (PRP) in the site of operation and forming a fascia and closing the

wound  
**Category**  
Treatment - Drugs

## 2

**Description**  
Injection of normal saline in the site of operation and forming a fascia and closing the wound

**Category**  
Placebo

## Recruitment centers

### 1

**Recruitment center**  
**Name of recruitment center**  
Shahid Chamran hospital  
**Full name of responsible person**  
Fariborz Ghaffarpasand  
**Street address**  
Shahid Chamran hospital, Chamran Avenue, Shiraz  
**City**  
Shiraz

## Sponsors / Funding sources

### 1

**Sponsor**  
**Name of organization / entity**  
Trauma Research Center  
**Full name of responsible person**  
Shahram Paydar  
**Street address**  
Trauma Research Center, 2nd floor, Shahid Rajaei hospital, Chamran Avnue, Shiraz  
**City**  
Shiraz  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Trauma Research Center  
**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**  
Trauma Research Center, Shiraz University of Medical Sciences  
**Full name of responsible person**  
Fariborz Ghaffarpasand  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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## Person responsible for updating data

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*empty*  
**Study Protocol**  
*empty*  
**Statistical Analysis Plan**  
*empty*  
**Informed Consent Form**  
*empty*  
**Clinical Study Report**  
*empty*  
**Analytic Code**  
*empty*  
**Data Dictionary**  
*empty*

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**