

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

**Position**

MD/ Researcher

**Other areas of specialty/work**

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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*