Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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/µL 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

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Iran (Islamic Republic of)

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

Method of measurement
Physical examination

2

Description
Radiological cure rate

Timepoint
Postoperaive 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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Person responsible for scientific inquiries

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Name of organization / entity

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Other areas of specialty/work

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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