

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The study of the effect of local Erythropoietin injection on Bone union in patients with Tibiofibular fracture

Protocol summary

Study aim

Determination of the effect of local Erythropoietin injection on Bone union in patients with Tibiofibular fracture referring to Khatam ol Anbiya hospital in Zahedan .2017-2018

Design

In this research, 60 eligible patients with Tibiofibular fractures referring to khatam ol Anbia Hospital in Zahedan were chosen. Then, patients were randomly divided into two control and intervention groups.

Settings and conduct

Patients are divided into two intervention and control groups. Two weeks after the operation and under sterile conditions, 4000 IU of EPO (two vials) were injected in intervention group into the fracture site and the control group received the equivalent of placebo. Afterwards the patients were followed by physical examination and radiographic imaging every four weeks until union was confirmed.

Participants/Inclusion and exclusion criteria

Patients with Tibiofibular Fractures :Patients with Closed Fracture Type A,B: Fractures Caused by High Energy Trauma: Male Gender:Age 18 to 40 Years Patients with Multiple Lower Injuries, Metaphyseal and Isolated Tibial, Pathologic, Comminuted, Osteoporotic and Open Fractures Patients under Treatment with Steroids, Anticoagulants, Nonsteroidal Antiinflammatory Drugs, Calcium Channel Blockers and Nicotine Underlying Disease (Diabetes, Cardiovascular Disease, etc.)

Intervention groups

Intervention group: 30 patients with Tibiofibular fracture that Erythropoietin injected at the fracture site. Control group: 30 patients with Tibiofibular fracture that used the equivalent of placebo instead of Erythropoietin.

Main outcome variables

Duration of union: The duration between of surgery and time of Bone union based on radiography and clinical examination that is based on the month.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171224038039N1**

Registration date: **2018-02-21, 1396/12/02**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-21, 1396/12/02**

Update count: **0**

Registration date

2018-02-21, 1396/12/02

Registrant information

Name

Asma Salehi sangani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5412 3454

Email address

a.salehi@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-20, 1396/10/30

Expected recruitment end date

2018-05-21, 1397/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study of the effect of local Erythropoietin injection on Bone union in patients with Tibiofibular fracture

Public title

The study of the effect of Erythropoietin on Bone union

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with Tibiofibular fractures Patients with closed fracture type A,B Fractures caused by high energy of trauma Male gender Age between 18 to 40 years

Exclusion criteria:

Patients with multiple lower injuries, metaphyseal and isolated tibial, pathologic, comminuted, osteoporotic and open fractures Patients under treatment with Steroids, Anticoagulants, Nonsteroidal Antiinflammatory drugs, Calcium Channel Blockers and Nicotine Underlying disease (Diabetes, Cardiovascular disease, etc.)

Age

From **18 years** old to **40 years** old

Gender

Male

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Easy and accessible randomization , considering the entry criteria for random assignment , in an envelope, the card will be placed with the letter A, B. then, after surgery, one of the colleagues is asked to select a card from the envelope, if A is selected, in the intervention group and if B is selected, will be placed in the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

In spite of being informed about the study, the patient is not aware of the type of intervention involved, and the injection of Erythropoietin or placebo is done by an expert who is not involved in the outcome evaluation. Therefore, the outcome evaluator is unaware of the type of intervention.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Zahedan University of Medical Sciences

Street address

Dr Hesabi sq, Pardis complex

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2017-11-11, 1396/08/20

Ethics committee reference number

IR.ZAUMS.REC.13960228

Health conditions studied**1****Description of health condition studied**

Tibiofibular fracture

ICD-10 code

S82.2

ICD-10 code description

Fracture of shaft of tibia

Primary outcomes**1****Description**

Duration of union: The duration between of sugery and time of Bone union was based on radiography and clinical examination that is defined based on month.

Timepoint

At the beginning of the study and every 4 weeks after surgery

Method of measurement

Physical examination and radiographic imaging

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: 30 patients with Tibiofibular fracture that Erythropoietin injected at the fracture site.

Category

Treatment - Drugs

2

Description

Control group: 30 patients with Tibiofibular fracture that used the equivalent of placebo instead of Erythropoietin.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam Ol Anbia hospital

Full name of responsible person

Dr Arash Ghaffari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

125401-1805003

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

Yes

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Asma Salehi sangani

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Fax**Email**

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