Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 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 sugery 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

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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
Street address
Khatam Ol Anbia hospital, Rostam Sq
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Asma Salehi sangani
Position
Student
Latest degree
Medical doctor
Other areas of specialty/work
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Latest degree
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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