

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of titanium elastic nail, external fixator and casting on prevention of complications in closed diaphyseal tibial fracture in children between 5-12 years old

Protocol summary

Study aim

The aim of this study was to compare titanium elastic nail (TEN) and external fixator (EF) and plastering in diaphyseal closed tibia fracture in children aged 5 to 12 years

Design

The study was a clinical trial using a non-probability sampling method on 120 children 5 to 12 years old with diaphysis closed fracture treated with one of the external fixator and titanium elastic nail and casting techniques.

Settings and conduct

This clinical trial study was conducted in children aged 5 to 12 years old with Tibia diaphyseal closed fractures referred to Shahid Bahonar Hospital in 2016 and 2017.

Participants/Inclusion and exclusion criteria

Inclusion criteria :Children 5 to12 years old with transverse , oblique and long closed tibia fracture Non-inclusion: Pathological fractures; congenital deformities of the skeletal system ; metabolic diseases

Intervention groups

Intervention group1: Patients treated with titanium elastic nail Intervention group2:Patients treated with external fixator Intervention group3:Patients treated with casting

Main outcome variables

Infection, nonfusion, refracture, angulation and more than 1 cm limb difference, as well as patient satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190127042514N4**

Registration date: **2020-02-28, 1398/12/09**

Registration timing: **retrospective**

Last update: **2020-02-28, 1398/12/09**

Update count: **0**

Registration date

2020-02-28, 1398/12/09

Registrant information

Name

Halimeh Kameshki

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-11, 1396/06/20

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

2017-09-11, 1396/06/20

Actual recruitment end date

2018-10-02, 1397/07/10

Trial completion date

2018-10-02, 1397/07/10

Scientific title

Comparison of titanium elastic nail, external fixator and casting on prevention of complications in closed diaphyseal tibial fracture in children between 5-12 years old

Public title

Comparison of titanium elastic nail, external fixator and casting on prevention of complications in closed

diaphyseal tibial fracture

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Being at the age of 5-12 years old Closed diaphyseal fracture of the tibia
Exclusion criteria:
Open fracture Pathological fracture Metabolic disease
Congenital deformities of the skeletal system

Age
From **5 years** old to **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **120**
Actual sample size reached: **120**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kerman University of Medical Sciences
Street address
Ibn Sina avenue; Jahad Blvd
City
Kerman
Province
Kerman
Postal code
76198131592
Approval date
2017-12-17, 1396/09/26
Ethics committee reference number
IR.KMU.REC.1396.1878

Health conditions studied

1

Description of health condition studied
Diaphyseal closed tibia fracture
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Patient satisfaction
Timepoint
2, 6 and 12 months later
Method of measurement
Using the Medical Outcomes Study Short Form 12 (SF-12) and Oxford Score questionnaire according to surgical outcome criteria

2

Description
Non fusion
Timepoint
2, 6 and 12 months later
Method of measurement
Imaging evaluation

3

Description
Refracture
Timepoint
2, 6 and 12 months later
Method of measurement
Imaging evaluation

4

Description
Angulation
Timepoint
2, 6 and 12 months later
Method of measurement
Imaging evaluation

5

Description
Infection
Timepoint
2, 6 and 12 months later
Method of measurement
Physical examination

6

Description
Bone length difference (up to 1 cm)
Timepoint
2, 6 and 12 months later
Method of measurement

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Patients treated with titanium elastic nail : After choosing the appropriate anesthesia method, the patient was placed supine. The surgical technique began with a closed reduction on the axial axis. Then, under sterile conditions, two surgical incisions in length 20 mm from 10 to 30 mm from the proximal tibial growth plate were made under the fluoroscopic guide on both the inner and outer sides of the lower limb skin. To select the proper Nail diameter after estimating the narrowest part of the central bone channel by imaging the Flynn's equation was used: nail diameter = $0.4 \times$ the diameter of the medullary canal After selecting the appropriate Nail, drill the posterior middle part of proximal metaphysis near the posterior-inner edge of the tibia within 10 cm of the growth plate, then nail medial was inserted by T-handle and the nail end was inserted to the metaphysis. Then, 2 cm away from the nail. After Nail Medial placement, lateral Nail was inserted in the same way

Category

Treatment - Devices

2

Description

Intervention group 2: Patients treated with external fixator: In sterile conditions and under the guide fluorescence, the place of pin was identified and the incision was made. Then the bone and pin were inserted with the appropriate drill and a monolateral external fixator with two rods and four pins was inserted.

Category

Treatment - Devices

3

Description

Intervention group 3: Patients treated with casting: The patient was plastered with a long leg plaster at a knee angle of 20 to 40 degrees to prevent embolism and rest of the Gastrocnemius muscle as well as to provide rotational stability, prior to casting if there was significant displacement, under anesthesia in the emergency or operating room. reduction was done

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Bahonar hospital

Full name of responsible person

Dr Shahab Ilka

Street address

Qarani avenue

City

Kerman

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Kerman

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7613747181

Phone

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr Shahab Ilka

Street address

Haft Baghe Alavi

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1355576169

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Grant name

Grant code / Reference number

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

No

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Amirreza Mirzaei Sosafidi

Position

Residency of orthopedic

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

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Full name of responsible person

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Position

Residency of orthopedic

Latest degree

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Person responsible for updating data

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Position

Residency of orthopedic

Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No subscription required

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available