Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of Titanium Elastic Nail (TEN) application for fixation of femoral trunk fractures in children with medial and lateral or just lateral portal

Protocol summary

Study aim
Comparison of Titanium Elastic Nail (TEN) application for fixation of femoral trunk fractures in children with medial and lateral or just lateral portal

Design
This study is a randomized (simple random) and single-blind clinical trial with parallel groups and in phase 2-3 that will be performed in Shohada Hospital in Tabriz.

Settings and conduct
This clinical trial study will be performed in Shohada Hospital of Tabriz with the participation of 40 children with femoral trunk fractures. Patients will be blind during this study. Patients will be divided into two groups after randomization (dice roll); for one group, TEN will be operated with lateral portal and the other with TEN with two medial and lateral portals.

Participants/Inclusion and exclusion criteria
Inclusion criteria include: unilateral or bilateral femoral trunk fracture and age range of 5 to 16 years and exclusion criteria also include: patients with open femoral fracture.

Intervention groups
In this randomized, single-blind clinical trial study, 40 patients were divided into two groups of 20 patients. For the first group, using TEN with lateral portal and the second group with TEN with two medial and lateral portals will be operated.

Main outcome variables
Pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20161101030637N3**
Registration date: **2021-11-04, 1400/08/13**
Registration timing: **prospective**

Last update: **2021-11-04, 1400/08/13**
Update count: **0**

Registration date
2021-11-04, 1400/08/13

Registrant information

Name
hossein aslani

Name of organization / entity
tabriz university of medical scienses

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-21, 1400/08/30

Expected recruitment end date
2022-03-20, 1400/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of Titanium Elastic Nail (TEN) application for fixation of femoral trunk fractures in children with medial and lateral or just lateral portal

Public title

TEN application for fixation of femoral trunk fractures in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Unilateral or bilateral femoral trunk fracture Age range 5 to 16 years

Exclusion criteria:

Patients with open femoral fractures

Age

From **5 years** old to **16 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

This study is a randomized (simple random) and single-blind clinical trial with parallel groups and in phase 2-3 that will be performed in Shohada Hospital in Tabriz.It should be noted that patients will be unaware of the type of groupings and randomly (dice roll was used for simple randomization. For patients in the first intervention group, odd numbers were considered and for patients in the second group, even numbers in Were considered) were divided into two groups .

Blinding (investigator's opinion)

Single blinded

Blinding description

The patients studied in this study will be unaware of the type of grouping.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Azadi Ave, Tabriz University of Medical Sciences

City

Tabriz

Province

East Azarbaijan

Postal code

5981764863

Approval date

2021-02-08, 1399/11/20

Ethics committee reference number

IR.TBZMED.REC.1399.1064

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

G89.11

ICD-10 code description

Acute pain due to trauma

Primary outcomes

1

Description

Pain

Timepoint

Three times a day for a week

Method of measurement

Visual scale of pain

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients will be randomly placed in this group. After anesthesia, patients will have surgery using Titanium Elastic Nail (TEN) with lateral portal femoral trunk fracture and will be examined for one week from the release of pain intensity (three times a day)

Category

Treatment - Devices

2

Description

Intervention group: Intervention group: Patients will be randomly placed in this group. After anesthesia, patients will be operated on using TEN with two medial and lateral portals of their femoral bone fracture and for one week from the release of pain intensity (three times a day).) Will be checked.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Shohada Hospital

Full name of responsible person
Hossein Aslani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
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Grant name

Grant code / Reference number

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

Title of funding source
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Hossein Aslani

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Orthopedics

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Person responsible for updating data

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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