

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3389 3765

Email address

aslanih@tbzmed.ac.ir

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

Street address

Golshahr Ave, Shohada Hospital

City

Tabriz

Province

East Azarbaijan

Postal code

5981764863

Phone

+98 41 3336 3982

Email

Dr.aslani73@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Samiei

Street address

Azadi Ave, Tabriz University of Medical Sciences

City

Tabriz

Province

East Azarbaijan

Postal code

5981764863

Phone

+98 41 3336 3982

Email

Samiei.moh@gmail.com

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

Street address

Golshahr Ave, Shohada Hospital

City

Tabriz

Province

East Azarbaijan

Postal code

5981764863

Phone

+98 41 3336 3982

Email

Dr.aslani73@yahoo.com

Person responsible for scientific 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

Street address

Golshahr Ave, Shohada Hospital

City

Tabriz

Province

East Azarbaijan

Postal code

5981764863

Phone

+98 41 3336 3982

Email

Dr.aslani73@yahoo.com

Person responsible for updating data

Contact**Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Hossein Aslani

Position

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Email

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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