

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Comparison of Outcomes of Tibial Shaft Fractures Treated by Dynamic Compression Plate and Intramedullary Nail

Protocol summary

Study aim

Comparison of Outcomes of Tibial Shaft Fractures Treated by Dynamic Compression Plate and Intramedullary Nail

Design

Clinical trial with control group, with parallel groups, randomized, on 60 patients. The rand function of Excel software was used for randomization.

Settings and conduct

In this double-blind clinical trial study, all patients who undergo orthopedic surgery at Shahid Beheshti Hospital in Babol are included in the study.

Participants/Inclusion and exclusion criteria

The criteria for entering the study include: age 15 to 65 years, fracture following acute trauma, the presence of a fracture in the diaphysis of the tibia, and having consent to enter the study, and the exclusion criteria include: a history of tibial bone fracture in two lower limbs, previous non-union, open fracture, history of underlying bone disease, history of tibial bone fracture in two lower limbs, peroneal nerve damage, accompanied by proximal or distal fracture.

Intervention groups

The first group is operated by Nile's intramedullary method, where the rods are made by Oswe company and are made of steel. The second group is done by the Dynamic Compression Plate method, fixing the bone with AO dynamic compression plate made by Oswe company, with at least 8 narrow holes.

Main outcome variables

Milionion, non-union, delayed union, pain, tenderness, infection of the operation area

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221029056333N2**

Registration date: **2023-01-23, 1401/11/03**

Registration timing: **registered_while_recruiting**

Last update: **2023-01-23, 1401/11/03**

Update count: **0**

Registration date

2023-01-23, 1401/11/03

Registrant information

Name

Mehdi Tavasoli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3225 6285

Email address

m.tavasoli@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-27, 1401/10/06

Expected recruitment end date

2023-01-26, 1401/11/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Outcomes of Tibial Shaft Fractures Treated by Dynamic Compression Plate and Intramedullary Nail

Public title

Comparison of two surgical methods Dynamic

Compression Plate and Intramedullary Nail of tibial shaft

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having the age of 15 to 65 years Fracture formation following acute trauma The presence of a fracture in the diaphysis of the tibia

Exclusion criteria:

History of tibial bone fracture in two lower limbs Previous failure Open fracture History of underlying bone disease History of tibial bone fracture in two lower limbs Peroneal nerve damage Associated with proximal or distal fracture

Age

From **16 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization is done using permutation blocks. Other blocks are considered 4. The ratio of two groups in each block is considered as 1:1. The Dynamic Compression Plate group is marked with A and the Intramedullary Nail group is marked with B. The creation of a random order in each block is done by a statistician.

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 Babol University of Medical Sciences

Street address

Babol University of Medical Sciences, Ganjafrooz Street, Babol, Mazandaran, Iran

City

Babol

Province

Mazandaran

Postal code

4716681451

Approval date

2022-11-27, 1401/09/06

Ethics committee reference number

IR.MUBABOL.HRI.REC.1401.189

Health conditions studied

1

Description of health condition studied

Fracture of shaft of tibi

ICD-10 code

S82.2

ICD-10 code description

Fracture of shaft of tibia

Primary outcomes

1

Description

Knee pain after rod insertion

Timepoint

2 weeks, 4 weeks and 8 weeks and 12 weeks and two months after surgery

Method of measurement

Using the VAS scale & record severe pain intensity

Secondary outcomes

1

Description

Millionaire

Timepoint

12 weeks to 6 months after surgery

Method of measurement

Based on examination and radiography

2

Description

Not welding

Timepoint

6 months after surgery

Method of measurement

Based on examination and radiography

3

Description

Delay in welding

Timepoint

3-6 months after surgery

Method of measurement

Based on examination and radiography

4

Description

Infection after surgery

Timepoint

2 weeks, 4 weeks, 8 weeks, 12 weeks and two months after surgery

Method of measurement

Based on the findings of the examination, including warmth, swelling, erythema, pus discharge, and radiography

Intervention groups

1

Description

Intervention group: They are operated by Nile's intramedullary group method, where the rods are manufactured by Oswe company and are made of steel.

Category

Treatment - Surgery

2

Description

Control group: Using the Dynamic Compression Plate method, bone fixation is performed with AO Dynamic Compression Plate made by Asoeh Company, with at least 8 narrow holes.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Dr. Mehdi Tavasoli

Street address

Babol University of Medical Sciences, Ganjafrouz Street, Babol, Mazandaran, Iran

City

Babol

Province

Mazandaran

Postal code

4716681451

Phone

+98 11 3225 6285

Email

m.tavasoli@mubabol.ac.ir

Web page address

<https://mubabol.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr. Mehdi Rajabnia

Street address

Babol University of Medical Sciences, Ganjafrouz Street, Babol, Mazandaran, Iran

City

Babol

Province

Mazandaran

Postal code

4716681451

Phone

+98 11 3219 7667

Email

ramazan@yahoo.com

Web page address

<https://mubabol.ac.ir/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Dr. Mohammad Mehdi Taziki

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Babol University of Medical Sciences; Ganjafrouz Street; Babol; Iran

City

Babol

Province

Mazandaran

Postal code

4716681451

Phone

+98 11 3225 6285

Email

mahdi.taziki@gmail.com

Web page address

<https://mubabol.ac.ir/>

Person responsible for scientific inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr. Mehdi Tavasoli

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Babol University of Medical Sciences; Ganjafrooz Street; Babol; Iran

City

Babol

Province

Mazandaran

Postal code

4716681451

Phone

+98 11 3225 6285

Email

Mehdi.tavasolii@gmail.com

Web page address

<https://mubabol.ac.ir/>

Person responsible for updating data

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr. Mehdi Tavasoli

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Babol University of Medical Sciences; Ganjafrooz Street; Babol; Iran

City

Babol

Province

Mazandaran

Postal code

4716681451

Phone

+98 11 3225 6285

Email

Mehdi.tavasolii@gmail.com

Web page address

<https://mubabol.ac.ir/>

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**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