

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Comparison of Minimal Invasive and conventional plating methods in treatment of Tibia shaft fracture

#### Protocol summary

##### Study aim

Comparison of Minimal Invasive and conventional plating method in the treatment of tibial shaft fractures

##### Design

In this research, 40 patients with Tibia shaft fracture are enrolled according to inclusion and exclusion criteria and then randomly assigned to two intervention and control groups by random number table.

##### Settings and conduct

In this research, 40 patients with Tibia shaft fracture referring to Shahid Rahnemon Hospital during the period 2017.22.11 to 2022.22.11 are enrolled according to inclusion and exclusion criteria.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with tibial shaft fracture; age range between 18 and 70 years; duration between fracture to surgery less than a week; just types A and B according to AO classification system; informed consent. Exclusion criteria: Patients with fractures in other organs; open fractures; head injuries lead to admitting the ICU; presence of burns to the same organ.

##### Intervention groups

Treatment of Tibia shaft fracture in the intervention group is performed by Minimal Invasive surgery and conventional surgery is used in the control group. In both groups, patients undergo postoperative visits and dressing will be performed one week after surgery. Sutures are removed on second week, and every 3 weeks visit is done with X-ray. When 3 of 4 cortices of Tibia get union, back to work without crutches are allowed.

##### Main outcome variables

union time : knee range of motion : infection

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20161225031559N2**

Registration date: **2018-01-21, 1396/11/01**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-01-21, 1396/11/01**

Update count: **0**

##### Registration date

2018-01-21, 1396/11/01

##### Registrant information

###### Name

Seyed Hossein Saeed-Banadaky

###### Name of organization / entity

Shahid Sadoughi Medical University

###### Country

Iran (Islamic Republic of)

###### Phone

+98 35 3626 0001

###### Email address

saeed@ssu.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice-chancellor for research Yazd Shahid Sadoughi University of medical sciences

##### Expected recruitment start date

2017-11-22, 1396/09/01

##### Expected recruitment end date

2022-11-22, 1401/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of Minimal Invasive and conventional plating methods in treatment of Tibia shaft fracture

**Public title**

Comparison of 2 plating technique

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

patients with tibial shaft fracture Age range between 18 and 70 years Duration from fracture to surgery less than a week Just types A and B fracture according to AO classification system Informed consent

**Exclusion criteria:**

Patients with fractures in other organs Patients with open fractures head injuries lead to admitting the ICU Burns to the same organ delayed operation more than one week

**Age**

From **18 years** old to **70 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study through simple random method with the table of random numbers patients assigned to two groups.

**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 Yazd Shahid Sadoughi University of Medical Sciences

**Street address**

Shahid Sadoughi University of Medical Sciences, Bahonar Sq, Yazd.

**City**

Yazd

**Province**

Yazd

**Postal code**

8916978477

**Approval date**

2017-10-02, 1396/07/10

**Ethics committee reference number**

IR.SSU.REC.1396.118

**Health conditions studied****1****Description of health condition studied**

Tibia shaft fracture

**ICD-10 code**

S82.2

**ICD-10 code description**

Fracture of shaft of tibia

**Primary outcomes****1****Description**

three of four cortex union time according to x-ray

**Timepoint**

One week after the surgery, 2 weeks after the surgery, and then every 3 weeks

**Method of measurement**

Physician examination and X-ray results

**Secondary outcomes****1****Description**

nonunion

**Timepoint**

From the fifth week after surgery

**Method of measurement**

X-ray results

**2****Description**

Infection

**Timepoint**

One week after surgery, 2 weeks after surgery, and then every 3 weeks

**Method of measurement**

Physician examination by specialist

**3****Description**

The need for re-surgery

**Timepoint**

2 weeks after the surgery and then every 3 weeks

**Method of measurement**

Physician examination by specialist

**Intervention groups****1****Description**

Control group: After induction of anesthesia and stabilization of vital signs, the open reduction, and the fixation are completed with the plate. The surgical procedure is such that after anesthesia the patient is placed on a standard radiolucent table. After the preparation of the limb, bone exposes with the longitudinal incision on the anterior aspect of leg in the fracture site and bone fixation is done with 8 hole 4.5 millimeter-plate and its screws. Wound closes in various layers under the drain. Dressing and short-leg splint are applied.

**Category**

Treatment - Surgery

**2****Description**

Intervention group: After induction of anesthesia and stabilization of vital signs, the reduction, and the fixation are completed with the plate. The surgical procedure is such that after anesthesia the patient is placed on a standard radiolucent table. After the preparation of the limb, bone exposes with two small longitudinal incisions in the proximal and distal parts of fracture. Then the reduction is done in a closed manner and controlled by fluoroscopy. Using a 3.5-millimeter locking plate and its screws fixation are performed without opening the fracture site. The plate is guided from the upper incisions to the distal, and fix with three screws in the proximal and three screws in distal. Wound closes in various layers under the drain. Dressing and short-leg splint are applied.

**Category**

Treatment - Surgery

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Shahid Doctor Rahneemoon Hospital

**Full name of responsible person**

Seyed Hossein Saeed

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Shahid Doctor Rahneemoon Hospital, Farrokhi Street, Yazd.

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saeed@ssu.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research, Yazd Shahid Sadoughi University of Medical Sciences

**Full name of responsible person**

Amir Houshang Mehrparvar

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ahmehrparvar@ssu.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, Yazd Shahid Sadoughi 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**

Yazd Shahid Sadoughi University of Medical Sciences

**Full name of responsible person**

Amir Houshang Mehrparvar

**Position**

Vice chancellor for research

**Latest degree**

Specialist

**Other areas of specialty/work**

Occupational Medicine

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Yazd Shahid Sadoughi University of Medical Sciences

**Full name of responsible person**

Seyed Hossein Saeed Banadaki

**Position**

fellowship in hand and upper extremity surgery

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Orthopedics

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Department of Orthopedics, Shahid Doctor

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Yazd Shahid Sadoughi University of Medical Sciences

**Full name of responsible person**

Seyed Hossein Saeed Banadaki

**Position**

fellowship in hand and upper extremity surgery

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Orthopedics

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**Web page address****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