

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### The impact of timing of tourniquet release on knee range of motion of patients with plating of tibia fractures: a randomized controlled trial

#### Protocol summary

##### Summary

This prospective, randomized study is designed to compare the impact of tourniquet release timing on plating of acute extraarticular tibia fracture. Inclusion criteria include age over 18 years and less than 55 years, surgery within the first week after fracture, closed and extraarticular tibia fractures, knee range of motion of more than 135 degrees and exclusion criteria consist of tourniquet time greater than 90 minutes; need for re-operation; patient's reluctance to cooperate in any of stage of the study; and patient's death. The study will be performed on 40 patients. Convenience sampling will be performed, and the participants will later be randomly allocated into two groups A and B (n=20 per group). Group A includes patients with tourniquet release during surgery and hemostasis before wound closure; Group B consists of patients with tourniquet deflation after wound closure and compression bandage. The data needed will be collected through interviews and observation, and studying patients' files. Range of knee motion in all patients before surgery and 24 hours and 14 days after surgery will be calculated with a standard 30 cm goniometer. Status of wound healing in all patients will be assessed 24 hours and 14 days after operation using the REEDA scale. Their pain will be assessed via visual analogue scale before surgery, 24 hours and fourteen days after operation.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015092824252N1**  
Registration date: **2016-05-20, 1395/02/31**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-05-20, 1395/02/31

##### Registrant information

###### Name

Maryam Khodabakhshi

###### Name of organization / entity

Birjand University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 56 3247 3655

###### Email address

horyms@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for research of Birjand University of Medical Sciences

##### Expected recruitment start date

2016-01-21, 1394/11/01

##### Expected recruitment end date

2016-06-21, 1395/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The impact of timing of tourniquet release on knee range of motion of patients with plating of tibia fractures: a randomized controlled trial

##### Public title

Effects of the timing of tourniquet release in orthopedic surgery

##### Purpose

Prevention

## Inclusion/Exclusion criteria

Inclusion criteria: Age over 18 years and less than 55 years; doing surgery within the first week after fracture; closed and extraarticular tibia fracture; absence of another fracture in any of the limbs; absence of chest, head or abdomen trauma; absence of vascular and nerve damage, the compartment syndrome and a history of previous surgery on the lower limbs; absence of clotting problems, peripheral vascular disease, peripheral neuropathy and pre-operative DVT limb; non-use of steroidal and non-steroidal anti-inflammatory drugs, anticoagulation, chemotherapy, smoking and narcotics; systolic blood pressure less than 20 mm Hg; body mass index less than 30; knee range of motion of more than 135 degrees Exclusion criteria: Tourniquet time greater than 90 minutes; need for re-operation; patient's reluctance to cooperate in any stage of the study; patient's death

## Age

From **18 years** old to **55 years** old

## Gender

Both

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **40**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

Through block randomization, blocks of individuals are selected, and treatment protocol is randomly allocated to them.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Birjand University of Medical Sciences

##### Street address

Ayatollah Ghaffari Street

##### City

Birjand

##### Postal code

9717853577

#### Approval date

2016-01-11, 1394/10/21

#### Ethics committee reference number

REClr.bums.1394.84

## Health conditions studied

### 1

#### Description of health condition studied

Fracture

#### ICD-10 code

S82.1

#### ICD-10 code description

Fracture of upper end of tibia

### 2

#### Description of health condition studied

Fracture

#### ICD-10 code

S82.2

#### ICD-10 code description

Fracture of shaft of tibia

### 3

#### Description of health condition studied

Fracture

#### ICD-10 code

S82.3

#### ICD-10 code description

Fracture of lower end of tibia

## Primary outcomes

### 1

#### Description

Knee Range of Motion

#### Timepoint

Before surgery, 24 hours and 14 days after surgery

#### Method of measurement

Goniometer

### 2

#### Description

wound healing

#### Timepoint

preoperatively, 24 hours and 14 days after operation

#### Method of measurement

REEDA scale

## Secondary outcomes

### 1

#### Description

pain

#### Timepoint

Before surgery, 24 hours and 14 days after surgery

#### Method of measurement

## Intervention groups

### 1

#### Description

Intervention group 1: Cuff of tourniquet will be applied on the most muscular part of the femur before surgery prep. The tourniquet used involves the MICROBACE pneumatic tourniquet system with the length of 75 cm and width of 15 cm, which will be applied between the skin and cuff over three layers of cast padding. After raising limb for 3 minutes and draining the blood, a pressure of 150 mm Hg higher than systolic blood pressure will be applied. Upon fracture reduction and fixation with plat and screws, tourniquet will be opened during surgery and before closing the wound.

#### Category

Treatment - Surgery

### 2

#### Description

Cuff of tourniquet will be applied on the most muscular part of the femur before surgery prep. The tourniquet used involves the MICROBACE pneumatic tourniquet system with the length of 75 cm and width of 15 cm, which will be applied between the skin and cuff over three layers of cast padding. After raising limb for 3 minutes and draining the blood, a pressure of 150 mm Hg higher than systolic blood pressure will be applied. Upon fracture reduction and fixation with plat and screws, the skin and other anatomical layers will be stitched and tourniquet will be opened after closing the wound and applying compression bandage.

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Reza Hospital

##### Full name of responsible person

Maryam Khodabakhsh, Surgical Technologist, Master Student in Nursing Education

##### Street address

Imam Reza Hospital, Ayatollah Taleghani Street

##### City

Birjand

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for research of Birjand University of Medical Sciences

#### Full name of responsible person

Gholamreza Sharifzadeh

#### Street address

Birjand University of Medical Sciences: Ayatollah Ghaffari Street

#### City

Birjand

#### 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 of Birjand University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

empty

#### Domestic or foreign origin

empty

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

empty

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Birjand University of Medical Sciences

##### Full name of responsible person

Maryam Khodabakhshi

##### Position

Surgical Technologist, Master's Student

##### Other areas of specialty/work

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## Person responsible for scientific inquiries

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Orthopedic Surgeon

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*