

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

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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

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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

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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

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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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