Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effects of knee immobilizer and skin traction in pain management of patients with peri-trochanteric fracture

Protocol summary

Study aim

Comparing the effects of using knee immobilizer and skin traction in pain management in patients with peritrochanteric fractures

Design

This study will be a three-arm, parallel-group, nonblinded, randomized, active-controlled trial.

Settings and conduct

A total of 75 patients with peritrochantric fracture in the orthopedic ward of the Imam Hossein will randomly be divided into three groups. Patients in the treatment groups will receive the study interventions, including knee immobilizer or skin traction, and in the control group will receive the standard analgesia protocol without any additional intervention. No blinding will be performed in this study.

Participants/Inclusion and exclusion criteria

Patients aged 40 to 70 who have peritrochanteric fractures and are aware of their pain level will be included in this study. Exclusion criteria are patients with multiple trauma or concurrent fractures and hepatic or renal dysfuntion.

Intervention groups

In this study, patients will be randomly divided into three groups, including skin traction, knee immobilizer, and control. The two intervention groups including the skin traction and knee immobilizer ones will receive the interventions during the preoperative course and patient hospitalization. The control group will receive no additional intervention for pain management except for the standard analgesia protocol.

Main outcome variables

The visual analog scale (VAS, 0-10) for pain at rest.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221226056923N1**
Registration date: **2023-06-03, 1402/03/13**
Registration timing: **prospective**

Last update: **2023-06-03, 1402/03/13**
Update count: **0**

Registration date

2023-06-03, 1402/03/13

Registrant information

Name

Farzad Amouzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of knee immobilizer and skin traction in pain management of patients with peri-trochanteric fracture

Public title

Analgesic effect of knee immobilizer and skin traction in pertrochantric fracture

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 40 and 70 patients with peri-trochantric fractures Patients who are neurologically oriented and aware of their pain

Exclusion criteria:

Patients who have multiple trauma or those with fractures in other bones Obesity (BMI > 35) Patients with renal and/or hepatic disorders Patients who are diagnosed with Myasthenia Gravis, Dermatitis or have delusions Opium addict patients

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned into three groups using block randomization. For randomization, no stratification will be performed. For block randomization “R” version 3.6.3 (R Foundation for Statistical Computing, Vienna, Austria), RStudio, and "blockrand" package will be used (randomization tool will be statistical computer software). For allocation concealment, sealed opaque envelops will be used.

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 Shahid Beheshti University of Medical Sciences

Street address

7th Floor, Building Number 2, Shahid Beheshti University of Medical Sciences, Arabi Avenue, Daneshjoo Boulevard, Velenjak, Tehran, Iran

City

Tehran

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Approval date

2022-08-14, 1401/05/23

Ethics committee reference number

IR.SBMU.RETECH.REC.1401.337

Health conditions studied

1

Description of health condition studied

Pertrochanteric fracture of femur

ICD-10 code

S72.1

ICD-10 code description

Pertrochanteric fracture

Primary outcomes

1

Description

Visual analog scale (VAS) for pain at rest

Timepoint

0, 12, AND 24 h after the hospitalization and daily afterward up to the time of operation

Method of measurement

Visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: In the intervention group 1, patients will receive the study intervention, including the knee immobilizer during their hospitalization and before the operation. Knee immobilizer is a removable device that maintains the stability of the knee. In addition, patients will receive the standard protocol for the preoperative analgesia. The standard protocol will be IV acetaminophen (Apotel) 1 g every 12 h and IV morphine sulfate 5 g as needed.

Category

Treatment - Devices

2

Description

Intervention group 2: In the intervention group 2, patients will receive the study intervention, including the skin traction during their hospitalization and before the operation. Traction is a directional pull on an extremity. In addition, patients will receive the standard protocol for

the preoperative analgesia. The standard protocol will be IV acetaminophen (Apotel) 1 g every 12 h and IV morphine sulfate 5 g as needed.

Category

Treatment - Devices

3

Description

Control group: Patients in the control group will only receive the standard protocol for preoperative analgesia without any additional intervention. The standard protocol will be IV acetaminophen (Apotel) 1 g every 12 h and IV morphine sulfate 5 g as needed.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein hospital

Full name of responsible person

Farzad Amouzadeh Omrani

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Tehran, Shahid Madani Avenue, Imam Hossein Hospital

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohammad Ali Abdollahzadeh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

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Person responsible for scientific inquiries

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Person responsible for updating data

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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