

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Effect of preoperative skin traction in pain control of patient with low energy fractures of hip

Protocol summary

Study aim

The purpose of this study is to evaluate the effect of traction on preoperative pain in patients with hip fractures.

Design

A randomized, parallel, single-blind trial which is randomized with "random allocation" software. The sample size for each group with a confidence interval of 95% is 42. Groups: One group will undergo skin traction until the surgery(Intervention group), and for the other group a pillow will be located under the affected lower limb (Control group).

Settings and conduct

The patients' treatment plans are written in sealed envelopes. No one is aware of the contents until it gets open in front of the patient. Based on the treatment plan each patient will be either in the intervention or in the control group. The severity of pain will be measured before and 2 hours after Traction application and every day until surgery using Visual Analogue Score(VAS). Opioid administration will also be documented as a confounding factor.

Participants/Inclusion and exclusion criteria

-Candidates for hip surgery due to low energy hip fractures admitted in the Kashani hospital. -Signing the consent form.

Intervention groups

Intervention group: Patients for whom skin traction will be loaded and their pain will be measured until the operation. Control group: Patients for whom skin traction will not be loaded and a pillow will be located under their knees and their pain will be measured until the operation.

Main outcome variables

Pain severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180729040636N3**

Registration date: **2020-07-01, 1399/04/11**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-01, 1399/04/11**

Update count: **0**

Registration date

2020-07-01, 1399/04/11

Registrant information

Name

Hossein Akbari aghdam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3620 2085

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-15, 1399/03/26

Expected recruitment end date

2020-07-16, 1399/04/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of preoperative skin traction in pain control of patient with low energy fractures of hip

Public title

Skin traction's effect on the preoperative pain in hip fractures

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Candidates for hip surgeries due to low energy hip fractures who admit Kashani hospital (Low-energy hip fractures) Signing the consent form (Consent)

Exclusion criteria:

Concomitant fractures with the hip fracture (Concomitant fractures) Neurological conditions of which the patient is unable to percept pain (Neurological issues) Drug abuse in any sense (Addiction)

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization will be done by the "random allocation" software. Each patient will be allocated as control or intervention based on this random allocation.

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 Isfahan University of Medical Sciences

Street address

Medical Isfahan university, Hezarjerib street, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2020-06-01, 1399/03/12

Ethics committee reference number

IR.MUI.MED.REC.1399.189

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

Low energy hip fractures

ICD-10 code

M84.359A

ICD-10 code description

Stress fracture, hip, unspecified, initial encounter for fracture

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

Severity of the pain

Timepoint

before intervention, 2 hours after intervention, daily measure until the surgery

Method of measurement

A horizontal line with the length of 100 millimeter is shown to the patient. the line is divided into ten equal segments (each 10 millimeters) numbered 0 to 10 (Visual Analogue Scale). The zero is named after no pain condition and 10 is introduced as the worst pain could exist. The patient is asked to mark the line based on his/her pain degree.

Secondary outcomes

empty

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

Intervention group: Patients undergoing skin traction.

Category

Treatment - Devices

2**Description**

Control group: Patients for whom the skin reaction will not be applied and a pillow under their knee of the affected side will be located instead.

Category

Treatment - Devices

Recruitment centers**1****Recruitment center**

Name of recruitment center

Ayatollah Kashani Hospital
Full name of responsible person
Hossein Akbari Aghdam
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Isfahan medical school, Hezarjeribstreet, Isfahan, Iran
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Isfahan 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
Esfahan University of Medical Sciences
Full name of responsible person

Hossein Akbari Aghdam
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Assistant professor
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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Title and more details about the data/document

The final main result will be shared.

When the data will become available and for how long

6 months after publication

To whom data/document is available

University researchers

Under which criteria data/document could be used

The data will be shared with researchers who will be writing a systematic review on the subject.

From where data/document is obtainable

Corresponding author

What processes are involved for a request to access data/document

The person should send an official email (with a valid institutional Email address) containing the Ethical code of his/him research project.

Comments