

# 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

akbariaghdam@med.mui.ac.ir

##### 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  
**Street address**  
Isfahan medical school, Hezarjeribstreet, Isfahan, Iran  
**City**  
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Akbariaghdam@med.mui.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Hossein Akbari Aghdam  
**Street address**  
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**Email**  
Akbariaghdam@med.mui.ac.ir  
**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  
**Position**  
Assistant professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Orthopedics  
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## Person responsible for scientific inquiries

#### Contact

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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**