

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Comparison of the effects two methods manual traction and automatic traction in femoral fractures surgery

#### Protocol summary

##### Study aim

Determining and comparing of the effects two methods manual traction and automatic traction in femoral fractures surgery

##### Design

Adults between 18 and 35 years old candidate for femoral fracture plate surgery Sample including a 10% increase in terms of the probability of loss, 65 people were Sampling will be performed using available non-probabilistic sampling

##### Settings and conduct

Shahid Bahonar and Shafa hospitals affiliated to Kerman University of Medical Sciences The first group will include patients who undergo femoral fracture plate surgery in the orthopedic ward of Shahid Bahonar and Shafa hospitals in Kerman and the traction in them is performed manually by the surgeon. The second group also includes patients who are in the period. The same fracture will be inserted by automatic traction method.

##### Participants/Inclusion and exclusion criteria

Need for femoral plate surgery:No infection before surgery:No bleeding diseases:Do not have any abnormalities in coagulation tests:No mental retardation:Lack of chronic underlying diseases (diabetes, cancer, etc.).

##### Intervention groups

The control group will include patients who undergo plaque surgery to treat femoral fractures, and traction in this Patients are performed manually by a surgical technologist. In this way, using 2 bone clamps, these two pieces of fracture are placed next to each other manually and with a lot of force by the surgical technologist.The intervention group includes patients whose fractures will be implanted by automatic traction method. Automatic traction is a new tool developed by the researcher of this project This tool performs traction during surgery regularly and continuously and requires additional personnel in Removes the surgical field.

##### Main outcome variables

The aim of the trial here is to investigate the effect of manual and automatic traction intervention on pain, fatigue and duration of surgery

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210110049987N1**

Registration date: **2021-02-13, 1399/11/25**

Registration timing: **prospective**

Last update: **2021-02-13, 1399/11/25**

Update count: **0**

##### Registration date

2021-02-13, 1399/11/25

##### Registrant information

##### Name

Farzad Abaszadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 4331 1539

##### Email address

f.abaszadeh@kmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-05-05, 1400/02/15

##### Expected recruitment end date

2022-03-06, 1400/12/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Comparison of the effects two methods manual traction and automatic traction in femoral fractures surgery

**Public title**  
Comparison of the effects two methods manual traction and automatic traction in femoral fractures surgery

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Need for femoral plate surgery  
**Exclusion criteria:**  
infection before surgery bleeding diseases any disturbance in coagulation tests mental retardation chronic underlying diseases (diabetes, cancer, etc.)

**Age**  
From **18 years** old to **35 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **65**

**Randomization (investigator's opinion)**  
Not randomized

**Randomization description**

**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 Kerman University of Medical Sciences

##### Street address

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran  
Postal Code: 7616913555

##### City

Kerman

##### Province

Kerman

#### Postal code

7616913555

#### Approval date

2021-01-04, 1399/10/15

#### Ethics committee reference number

IR.KMU.REC.1399.546

## Health conditions studied

### 1

#### Description of health condition studied

femoral fractures surgery

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Pain score in McGill Questionnaire

#### Timepoint

After surgery

#### Method of measurement

.McGill Pain Questionnaire

### 2

#### Description

The duration of surgery is calculated based on minutes according to the surgery

#### Timepoint

The duration of surgery is measured in minutes from the moment the surgeon declares the need for traction until the two broken pieces are placed side by side.

#### Method of measurement

Based on minutes spent using the clock at the surgery site

### 3

#### Description

The amount of musculoskeletal pain and discomfort based on the score obtained from the Nordic questionnaire

#### Timepoint

After surgery

#### Method of measurement

Nordic Ergonomics Questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: : The intervention group includes patients whose fractures will be implanted in the same

period of time by automatic traction method. Automatic traction (use in the femur) is a new tool developed by the researcher of this project (Patent application number: 139850140003002894 Patent number: 100601.) This tool performs traction during surgery regularly and continuously and requires additional personnel in Removes the surgical field.The holder plate of this device has 2 bases and each of these bases is connected to a circular ring that these rings have the ability to increase and decrease the diameter so that they can fit The patient's femur becomes large or small, and these rings have grooved sections that are necessary for fixation to the patient's bone

#### Category

Treatment - Surgery

## 2

#### Description

Control group: The control group will include patients who undergo plaque surgery in the orthopedic ward of Shahid Bahonar and Shafa hospitals in Kerman to treat femoral fractures, and traction (how to place separate bones next to each other) in this Patients are performed manually (traditional and common) by a surgical technologist. In this way, using 2 bone clamps (orthopedic tools), these two pieces of fracture are placed next to each other manually and with a lot of force by the surgical technologist, and then the surgeon fixes the plaque in the desired area with screws

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Bahonar and Shafa hospitals affiliated to Kerman University of Medical Sciences

##### Full name of responsible person

Farzad Abaszadeh

##### Street address

Kerman University of Medical Sciences,Medical University Campus,Haft-Bagh Highway, Kerman, Iran

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## Sponsors / Funding sources

### 1

#### Sponsor

#### Name of organization / entity

Kerman University of Medical Sciences

#### Full name of responsible person

Dr.Abbas Pardakhty, Vice Chancellor of Research and technologyKerman University of Medical Sciences

#### Street address

Ebn-e-Sina St.,Jahad Blvd., Kernan,Iran

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#### Province

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#### Postal code

postal code :7619813

#### Phone

+98 34 3132 5700

#### Email

KMU\_RESEARCH@YAHOO.COM

#### Web page address

<http://vresearch.kmu.ac.ir/fa>

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Kerman University of Medical Sciences

#### Proportion provided by this source

50

#### 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

Kerman University of Medical Sciences

##### Full name of responsible person

Farzad Abaszadeh

##### Position

Faculty member

##### Latest degree

Master

##### 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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**Full name of responsible person**  
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**Latest degree**  
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fabaszadeh99@gmail.com

## 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

Yes - There is 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

No - There is not a plan to make this available

### Title and more details about the data/document

All data is potentially shareable after unidentified individuals

### When the data will become available and for how long

Access period starts 6 months after the results are published

### To whom data/document is available

It will be available to researchers working in academic institutions and people working in industry

### Under which criteria data/document could be used

No special mechanism is required

### From where data/document is obtainable

fabaszadeh99@gmail.com

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

No special mechanism is required  
fabaszadeh99@gmail.com

### Comments