

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

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3132 5829

Email

fabaszadeh99@gmail.com

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 technology Kerman University of Medical Sciences

Street address

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

City

Kerman

Province

Kerman

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

Street address

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

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3226 4196

Email
fabaszadeh99@gmail.com

Person responsible for scientific 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
Street address
Kerman University of Medical Sciences, Medical
University Campus, Haft-Bagh Highway, Kerman, Iran
City
Kerman
Province
Kerman
Postal code
7616913555
Phone
+98 34 3226 4196
Email
fabaszadeh99@gmail.com

Person responsible for updating data

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

Kerman
Province
Kerman
Postal code
7616913555
Phone
+98 34 3226 4196
Email
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