

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of lesser trochanter fixation on hip flexion strength in patients with intertrochantric fx of femur in Karaj Madani hospital

Protocol summary

Study aim

Investigating the effect of lesser trochanter fixation on hip joint flexion strength in patients with femoral intertrochanteric fracture.

Design

Clinical trial with control group, double blind, randomized, phase 2 on 52 patients. Excel software was used for randomization.

Settings and conduct

Patients referred to Shahid Madani Medical Education Center during 1401 were randomly divided into two groups, in the intervention group, after the main surgery, the lesser trochanter was also fixed with a wire, and in the control group, was not fixed. Next, at 6-week, 3-month, and 6-month intervals, hip flexion strength will be compared with the opposite limb. The strength of hip joint flexion is measured manually and varies from zero-fifth to five-fifth. The examination of muscle strength is done by (Dr. Mohammad Sajjad Mir Hosseini), who is the project guide, and doesn't know which group the examinee belongs to.

Participants/Inclusion and exclusion criteria

Inc criteria: 1) Patients with intertrochanteric fracture of the femur with separation of the lesser trochanter referred to Shahid Madani Medical Training Center during 1401 2) Mastery of speech and understanding of Persian language 3) Consent to participate in the study 4) Age > 18 yrs
Exc criteria: 1) Lack of consent to participate in the study 2) Contraindications for surgery 3) Concomitant diseases that affect the power of limb flexion.

Intervention groups

Patients referred to Shahid Madani Medical Education Center during 1401 were randomly divided into two groups, in the intervention group, after the main surgery, the lesser trochanter was fixed with a wire, and in the control group was not fixed

Main outcome variables

flexion strength of the hip joint

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230117057145N1**

Registration date: **2023-02-26, 1401/12/07**

Registration timing: **registered_while_recruiting**

Last update: **2023-02-26, 1401/12/07**

Update count: **0**

Registration date

2023-02-26, 1401/12/07

Registrant information

Name

Hamid Sohrabian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3444 3284

Email address

hamiso1988@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-07-23, 1402/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of lesser trochanter fixation on hip flexion strength in patients with intertrochantric fx of femur in Karaj Madani hospital		help of wire. is done and the purpose of the study is to investigate the effect of fixation on hip flexion strength	
Public title	The effect of lesser trochanter fixation on hip flexion strength	Secondary Ids	empty
Purpose	Treatment	Ethics committees	
Inclusion/Exclusion criteria	Inclusion criteria: patients with intertrochantric fx of femur and lesser trochantric fx age over 18 years Exclusion criteria: Contraindications for surgery The presence of previous diseases that affect the flexion power of the limb and interfere with the examination process (such as neuromuscular diseases, stroke, limb paralysis, etc.) The patient's lack of consent to participate in the trial	1	
Age	From 18 years old	Ethics committee	
Gender	Both	Name of ethics committee	Ethics Committee of Alborz University of Medical Sciences
Phase	N/A	Street address	Taleghani Square, North Taleghani Blvd, Alborz University of Medical Sciences
Groups that have been masked	- Participant - Care provider - Outcome assessor - Data analyser - Data and Safety Monitoring Board	City	karaj
Sample size	Target sample size: 52	Province	Alborz
Randomization (investigator's opinion)	Randomized	Postal code	3149779453
Randomization description	Randomization among patients with simultaneous intertrochanteric fracture of the femur bone and separation of the lesser trochanter is a simple randomization method, the randomization unit is individual and using a table of random numbers.	Approval date	2022-12-03, 1401/09/12
Blinding (investigator's opinion)	Double blinded	Ethics committee reference number	IR.ABZUMS.REC.1401.251
Blinding description	Examination of muscle strength by only one orthopedic surgeon (Dr. Mohammad Sajjad Mir Hosseini) who is the master of the project It is carried out and the examiner is not aware of which group the examinee belongs to. Also the patients themselves are not aware of which group they are in (double blind).	Health conditions studied	
Placebo	Not used	1	
Assignment	Parallel	Description of health condition studied	intertrochanteric fx of femur
Other design features	Patients with the same type of fracture are divided into two groups. In the first or control group, routine and gold standard treatment of intertrochanteric fracture is performed. In the intervention group, in addition to routine and gold standard fracture treatment, fixation of the lesser trochanter of the femur is also done with the	ICD-10 code	S72.1
		ICD-10 code description	Pertrochanteric fracture
		Primary outcomes	
		1	
		Description	Flexion strength in patients with femoral intertrochanteric fracture
		Timepoint	Measuring hip flexion strength at intervals of 6 weeks, 12 weeks, 24 weeks (6 months)
		Method of measurement	manual muscle testing (from zero fifth to five fifth)
		Secondary outcomes	empty
		Intervention groups	
		1	
		Description	

Intervention group: patients with intertrochanteric fracture of the femur who simultaneously have separation of the lesser trochanter. In these patients, in addition to the surgical treatment of intertrochanteric fracture (using common methods such as using DHS plate or cephalomedullary nail, etc.), their femoral lesser trochanter is also fixed with the help of wire. To perform the intervention (fixation of the lesser trochanter), no other tool is needed except for the wire and its guide (wire passer).

Category

Treatment - Surgery

2**Description**

Control group: patients with simultaneous intertrochanteric fracture and separation of the lesser trochanter of the femur, who are treated commonly and routinely, but fixation of the lesser trochanter is not done in them.

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

shahid Madani hospital

Full name of responsible person

Hamid sohrabian

Street address

Mahan Boulevard, Madani Square, Shahid Madani Hospital

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Karaj University of Medical Sciences

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

Karaj 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**

Karaj University of Medical Sciences

Full name of responsible person

Hamid Sohrabian

Position

Resident of orthopaedic surgery

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All potential data can be shared after de-identifying individuals.

When the data will become available and for how long

The access period starts 6 months after the results are published.

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

The use of documents for research and scientific work is allowed.

From where data/document is obtainable

Applicants should contact the following email to use and receive documents: hamiso1988@gmail.com

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

In a period of less than a week, the applicants for receiving the documents who contacted by e-mail will be answered and the documents will be provided to them.

Comments