

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of internal fixation results of intracapsular fracture of the femoral neck by two methods of cannula screws and cancellous screws in osteoporotic patients

Protocol summary

Study aim

Comparison of internal fixation results of intracapsular fracture of the femoral neck by two methods of cannula screws and cancellous screws in osteoporotic patients

Design

In this clinical efficacy study, after the approval and obtaining the code of ethics and the IRCT code, 40 patients from all patients referred to Shahada Training Center in Tabriz who have a fracture inside the femoral neck capsule and are indicated for internal fixation with screws will be included in the study. Patients will be divided into two groups based on simple randomization method

Settings and conduct

40 people from all patients referred to Tabriz Martyrs Education Center

Participants/Inclusion and exclusion criteria

Eligible patients met all of the following inclusion criteria: (1) male or female with no upper age limit; (2) femoral neck fracture confirmed by radiography of the hip and femur, computed tomography, or magnetic resonance imaging (MRI). We will exclude patients who do not meet any of the following criteria: patients not suitable for intracapsular fixation (ie, severe osteoarthritis, rheumatoid arthritis, or pathologic fracture).

Intervention groups

First group: internal fixation with three 6.5 mm cannulated screws with inverted triangle method. The second group: internal fixation with three 6.5 mm cancellous screws with the inverted triangle method.

Main outcome variables

Stabilization in femoral neck fractures

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221113056482N1**

Registration date: **2023-02-21, 1401/12/02**

Registration timing: **retrospective**

Last update: **2023-02-21, 1401/12/02**

Update count: **0**

Registration date

2023-02-21, 1401/12/02

Registrant information

Name

Alireza Sadeghpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 939 550 2800

Email address

alirezasadeghpour17@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of internal fixation results of intracapsular fracture of the femoral neck by two methods of cannula

screws and cancellous screws in osteoporotic patients

Public title

Comparison of internal fixation results of intracapsular fracture of the femoral neck by two methods of cannula screws and cancellous screws in osteoporotic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Men or women with no upper age limit Femoral neck fracture confirmed by radiography of the hip and femur, computed tomography, or magnetic resonance imaging (MRI) Operative treatment of fractures within 4 days of visiting the emergency room, or operation of non-displaced fractures within 7 days of visiting the emergency room. The patient was ambulatory before the fracture, although she may have used an aid such as a cane or walker Predictive medical optimization for hip surgery Provision of informed consent by the patient or designated legal representative Do not have any other major trauma such as another fracture, according to the supervisor's judgment

Exclusion criteria:

Patients not suitable for intracapsular fixation (ie, severe osteoarthritis, rheumatoid arthritis, or pathologic fracture).

Age

From **45 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, the "Random Allocation Law" method was used so that the numbers for randomization were written on cards in order. Even numbers were considered for the first group (internal fixation with three cannulated screws of 6.5 mm with the inverted triangle method) and odd numbers for the second group (internal fixation with three cancellous screws of 6.5 mm with the inverted triangle method). In this method, the number of people assigned to each group will be balanced at the end of the study.

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 Tabriz University of Medical Sciences

Street address

Golgasht

City

Tabriz

Province

East Azarbaijan

Postal code

5167846171

Approval date

2022-08-29, 1401/06/07

Ethics committee reference number

IR.TBZMED.REC.1401.497

Health conditions studied

1

Description of health condition studied

Femoral neck fracture in osteoporotic patients

ICD-10 code

S72.0

ICD-10 code description

Fracture of head and neck of femur

Primary outcomes

1

Description

Fixation of intracapsular fracture of femoral neck

Timepoint

The patient is followed up in the clinic for two weeks, one month, three months, six months and annually for up to 3 years to record clinical and radiological results.

Method of measurement

After the operation, the clinical results will be evaluated in the form of scoring in each visit. Welding will be checked with graphs in face view with 15 degrees of internal rotation of the legs and profile view. The creation of trabeculae from between the fracture line will be considered as welding. Non-union is considered as no formation of said trabeculae, redistribution or progressive. Full weighting will be allowed by ensuring welding in the graph. If re-surgery is required, follow-up will be done before re-surgery.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: internal fixation with three 6.5 mm cannulated screws with inverted triangle method (standard treatment). After being fixed in the supine position in a special orthopedic bed, they receive spinal anesthesia or general anesthesia and undergo closed reduction under c-arm control. Then, with the standard lateral approach, the placement of the screws is determined with Kirschner rods.

Category

Treatment - Surgery

2

Description

Intervention group: Internal fixation with three 6.5 mm cancellous screws using the inverted triangle method.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Medical Research & Training Hospital

Full name of responsible person

Alireza Sadeghpour

Street address

Shohada Medical Research & Training Hospital,
Golshahr street

City

Tabriz

Province

East Azarbaijan

Postal code

5167846171

Phone

+98 41 3389 3765

Email

alirezasadeghpour17@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Parviz Shahabi

Street address

Third floor, Central building No. 2, Tabriz University of
medical Sciences, Golgasht Blvd., Tabriz city

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3336 4664

Email

parvizshahabi@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Alireza Sadeghpour

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Shohada Medical Research & Training Hospital,
Golshahr street

City

Tabriz

Province

East Azarbaijan

Postal code

5167846171

Phone

+98 41 3389 3765

Email

amir.valizadeh67@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Alireza Sadeghpour

Position

Professor

Latest degree

Specialist
Other areas of specialty/work
Orthopedics
Street address
Shohada Medical Research & Training Hospital,
Golshahr street
City
Tabriz
Province
East Azarbaijan
Postal code
5167846171
Phone
+98 41 3389 3765
Email
alirezasadeghpour17@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Alireza Sadeghpour
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Orthopedics
Street address
Shohada Medical Research & Training Hospital,
Golshahr street
City
Tabriz
Province
East Azarbaijan
Postal code

5167846171

Phone

+98 41 3389 3765

Email

alirezasadeghpour17@gmail.com

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

Not applicable

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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

After making people unidentifiable, the results will be published in the form of dissertations and articles

When the data will become available and for how long

Access starts After preparing the results

To whom data/document is available

All of the researchers

Under which criteria data/document could be used

Examining and expanding the results

From where data/document is obtainable

Shahab Mahdipour Email: shahab5mph@gmail.com

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

Contact by email up to one month after the request

Comments