Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of Cinnopar on reducing the complications of femoral neck fractures in people aged 40 to 60 years old

Protocol summary

Study aim

Evaluation of the effect of Cinnopar in reducing the complications of femoral neck fractures in people aged 40 to 60 years

Design

In this study, eligible patients were randomly divided into two groups of 15 each. Receive postoperative routine. Demographics and medical history of patients will be collected and information recorded, and identification will be performed in both groups. Patients are then visited on day 1, week 3, month 3 and month 6 after the operation. At each visit, the operation site is evaluated, radiographs are taken for radiographic union, or fixation failure is performed. Graphs for ionization or non-ionization or fixation failure will be approved by an orthopedic and radiologist colleague and analyzed by a statistical consultant.

Settings and conduct

Simple randomization. Random unit: individual. Randomization tool: random number table. Hide: use opaque envelopes sealed in random sequence. The study places are: Imam Khomeini and Golestan hospitals in Ahvaz.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patient consent to participate in the study; patients with femoral neck fractures in the ages of 40-60 years old. Exclusion criteria: patients who smoke; patients who consume alcohol; patients with a history of diabetes, chronic hypertension, rheumatoid arthritis, calcium metabolism disorders, cancer, Paget's disease and chronic renal failure; consumption of corticosteroids and PPI; patients with very high weight or very low weight.

Intervention groups

People with femoral neck fractures who, in addition to the usual treatments for femoral neck fractures, including anticoagulant antibiotics, etc., will also receive cinnopar as a supplement.

Main outcome variables

Union and non union rate; duration of return to activity; pain reduction rate; fixation failure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210118050072N1**
Registration date: **2021-02-18, 1399/11/30**
Registration timing: **prospective**

Last update: **2021-02-18, 1399/11/30**
Update count: **0**

Registration date

2021-02-18, 1399/11/30

Registrant information

Name
Mojtaba jafarzade jahromi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 71 5433 1137
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mojtaba.jafarzade@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2021-05-21, 1400/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of Cinnopar on reducing the complications of femoral neck fractures in people aged 40 to 60 years old

Public title
The effect of Cinnopar on reducing the complications of femoral neck fractures in people aged 40 to 60 years old

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patient consent to participate in the study Patients with femoral neck fractures in the ages of 40-60 years old

Exclusion criteria:
Smocking Alcohol consumption Patients with a history of diabetes, chronic hypertension, rheumatoid arthritis, calcium metabolism disorders, cancer, Paget's disease and chronic renal failure Corticosteroids and PPI user Patients with very high or very low weight

Age
From **40 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: simple randomization. Random unit: individual. Randomization tool: random number table. How to randomize a random sequence: first, we predetermine the table numbers to read (up, down, left and right). The even or odd numbers are in the control group or the case group. Then we put them on one of the numbers and in one moves in predetermined directions and records numbers and assigns them to different groups. Concealment: using opaque envelopes sealed with a random sequence. First the random sequence is specified with a table of random numbers and then a number of envelopes are prepared and each random sequence is recorded on a card and the cards are inside the envelope. The letters are placed in order and finally pasted in envelopes and placed inside a box, and after each patient's visit, one of the envelopes is opened in order, the assigned group of the participant is revealed.

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 Ahvaz Jundishapur University of Medical Sciences

Street address
Ahvaz, Farvardin St., Golestan Hospital

City
Ahvaz

Province
Khouzestan

Postal code
6193673111

Approval date
2021-02-16, 1399/11/28

Ethics committee reference number
IR.AJUMS.HGOLESTAN.REC.1399.152

Health conditions studied

1

Description of health condition studied
femoral neck fracture

ICD-10 code
S72.00

ICD-10 code description
Fracture of unspecified part of neck of femur

Primary outcomes

1

Description
Non- union

Timepoint
X_ray at first, after 3 weeks, after 3 months and after 6 months

Method of measurement
X-ray

2

Description
Time to return to activity

Timepoint
6 weeks and 3 months

Method of measurement
The patient walks independently and without pain and performs normal activities

3

Description
Reduce pain

Timepoint
After 3 months
Method of measurement
Visual Analogue Scale

4

Description
Fixation failure
Timepoint
2 weeks, 6 weeks, 3 months post operation
Method of measurement
x ray

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: people with femoral neck fractures in the ages of 40 to 60 years referred to the orthopedic ward of Golestan and Imam Khomeini hospitals in Ahvaz after division by simple randomization method who are in the intervention group in addition to the usual treatments for femoral neck fractures including surgery and internal fixation, anticoagulants, antibiotics treated with Cinnopar at a dose of 20 micrograms per day for one month. Then they are visited in the third, sixth and third month after the operation.
Category
Treatment - Drugs

2

Description
Control group: people with femoral neck fractures in the age of 40 to 60 years referred to the orthopedic ward of Golestan and Imam Khomeini hospitals in Ahvaz after being divided by simple randomization method who are in the control group treated with common femoral neck fractures including surgery and internal fixation, anticoagulants, antibiotics and then visit in the third, sixth and third week after surgery.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Khomeini hospital
Full name of responsible person
Mohamad Fakoor
Street address
Shohada Square. Azadegan Street
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6193673111
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Sahand Jorfi
Street address
Ahvaz Jundishapur University of Medical Sciences, Farvardin street
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Jorfi-s@ajums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Mojtaba Jafarzade Jahromi
Position
resident
Latest degree
Medical doctor

Other areas of specialty/work
Orthopedics
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Specialist
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Person responsible for updating data

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Latest degree
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Email
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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
No - There is not 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
At the end of the study, all data can be shared after unidentified individuals and will be available through the registration of information and the results in the relevant scientific sites
When the data will become available and for how long
From the year 1400
To whom data/document is available
Researchers working in academic institutions, physicians and medical students at different levels
Under which criteria data/document could be used
Orthopedic specialists can access the results of our studies by email or in person or by phone in order to choose an adjunct method for better healing of femoral neck fractures and to reduce the complications caused by these fractures.
From where data/document is obtainable
Mojtaba Jafarzade 09173917359
What processes are involved for a request to access data/document
Making a phone call, if the requested person is identified, they will be provided with prompt information
Comments