

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 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

##### Email address

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

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

6193673111

##### Phone

+98 61 3222 2114

##### Email

himam@ajums.ac.ir

## 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

##### City

ahvaz

##### Province

Khouzestan

##### Postal code

6193673111

##### Phone

+98 61 3222 2922

##### Email

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

**Street address**

Motahari hospital, Motahari Ave.

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**Province**

Fars

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7415713548

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mojtaba.jafarzade@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Mohamad fakoor

**Position**

professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Orthopedics

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Imam khomeini hospital, Azadegan Ave.

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**Email**

dr\_m\_fakoor@hotmail.com

**Person responsible for updating data****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****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**