Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

The effect of Cinnopar drug on the degree of healing and fracture union with mild distal radius trauma

Protocol summary

Study aim
Evaluation the effect of cinoppar drug on the degree of welding and improvement of fracture with mild distal Radius trauma

Design
Clinical trial with control group, community based and pragmatic, with parallel groups, one-way blinded, randomized

Settings and conduct
This srudy will be conducted at Zahedan Khatam Al-Anbiya Hospital. In this study the doctor is aware of the type of treatment but the patients themselves will be unaware of the treatment group and therefore the study will be single blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age over 45 years; single fracture of distal radius with low energy; fracture requiring reduction and plating. Exclusion criteria: fracture with displacement or surgical need; use of Cinnopar or its external model at the time of entry; fracture with high energy; use at least 4 weeks of bone resorption inhibitors such as bisphosphonates; history of chemotherapy or radiotherapy; history of urinary stones; hypercalcemia more than 10 mg per deciliter or hypercalciuria; developing advanced liver or kidney disorders; autoimmune diseases; smoking or drug abuse

Intervention groups
The control group will include 50 patients who will receive fracture treatment alone (reduction and plating). The intervention group is consisted of 50 patients who will receive Cinnopar (vial 250 µg/ml, manufactured by Sinagan Pharmaceutical Company), 20 micrograms subcutaneous injection daily in the morning for 8 weeks in addition to usual fracture treatment (reduction and plating). For all of the patients in the two groups, elemental calcium 1000 mg tablets will be prescribed daily and vitamin D 50,000 IUs capsules will be administered weekly.

Main outcome variables
Clinical improvement of fracture; Radiographic improvement of fracture (welding)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180526039837N1**
Registration date: **2018-06-06, 1397/03/16**
Registration timing: **registered_while_recruiting**

Last update: **2018-06-06, 1397/03/16**
Update count: **0**

Registration date
2018-06-06, 1397/03/16

Registrant information

Name
maryam Ashrafi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-02-28, 1395/12/10

Expected recruitment end date
2018-06-21, 1397/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Cinnopar drug on the degree of healing and fracture union with mild distal radius trauma

Public title
Effect of Cinnopar on forearm fracture healing
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Single radial distal fracture with low energy Fractures require close reduction and plastering
Exclusion criteria:
Fracture with displacement or need of surgery Fracture occurring with high energy Administration of bone resorption inhibitors such as bisphosphonates for at least 4 weeks History of chemotherapy or radiotherapy History of urinary stones Hypercalcemia more than 10 mg per deciliter or hypercalciuria Advanced liver or kidney disorder Autoimmune diseases Smoking or drug abuse
Age
From **45 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization, individual, random number table
Blinding (investigator's opinion)
Single blinded
Blinding description
The doctor is aware of the type of treatment but the patients themselves are unaware of the type of treatment they will receive.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Zahedan University of Medical Sciences
Street address
Dr.Hesabi Sq., Daneshgah Ave., Zahedan
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Approval date
2017-02-19, 1395/12/01
Ethics committee reference number
IR.ZAUMS.REC.1395. 97

Health conditions studied

1

Description of health condition studied
Distal radius fracture
ICD-10 code
S52.5
ICD-10 code description
Fracture of lower end of radius

Primary outcomes

1

Description
Clinical fracture improvement
Timepoint
Every two weeks for 8 weeks
Method of measurement
Based on an orthopedic physician examination, capability to get things, no movement restrictions, no pain

2

Description
Radiographic improvement of fracture(Welding)
Timepoint
Every two weeks for 8 weeks
Method of measurement
Based on radiological findings, bone formation and cortex stretching

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: receiving fracture treatment (reduction and plating) and then administering Cinnopar(250 µg/ml vial, manufactured by Sinagan Pharmaceutical Company), subcutaneous injection of 20 micrograms daily in the morning for 8 weeks plus daily administration of 1000 Mg of elemental calcium tablets

and weekly vitamin D capsules of up to 50,000 international units

Category

Treatment - Drugs

2

Description

Control group: receiving fracture treatment (reduction and plating) and then administration of 1000 Mg of elemental calcium tablets and weekly vitamin D capsules of up to 50,000 international units for 8 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Orthopedic Clinic of Khatam-ol-Anbia Hospital in Zahedan

Full name of responsible person

Dr. Arash Ghafari

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Khatam Al Anbia Hospital, Jamejam Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr Mohsen Taheri

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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

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Maryam Ashrafi

Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Position
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Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available