

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)

Phone

+98 54 3322 7521

Email address

dr.ashrafi@zaums.ac.ir

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

Street address

Khatam Al Anbia Hospital, Jamejam Blvd.

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9815733169

Phone

+98 54 3322 0501

Email

Dr.ghafari@zaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr Mohsen Taheri

Street address

Zahedan University of Medical Sciences, Dr. Hesabi Sq., Daneshgah Ave., Zahedan

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Phone

+98 54 3329 5744

Email

Dr.taheri@zaums.ac.ir

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

Street address

Ali-ebn Abi Talib Hospital, Salamat Blvd., Daneshgah Ave., Zahedan

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743111

Phone

+98 54 3329 5570

Email

Dr.ashrafi@zaums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr Arash Ghafari

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Operation room, Khatam-ol-Anbiya Hospital, Jamejam Blvd., Zahedan

City

Zahedan
Province
Sistan-va-Balouchestan
Postal code
9815733169
Phone
+98 54 3322 0501
Email
Dr.ghafari@zaums.ac.ir

Person responsible for updating data

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
Street address
Ali-ebn Abi Talib Hospital, Salamat Blvd., Daneshgah Ave., Zahedan
City
Zahedan
Province
Sistan-va-Balouchestan

Postal code
9816743111
Phone
+98 54 3329 5570
Email
Dr.ashrafi@zaums.ac.ir

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