

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Evaluation of the effect of teriparatide (cinopar) on bone healing in mandibular fracture

Protocol summary

Study aim

Evaluation of the effect of teriparatide (cinopar) on bone healing in mandibular fractures.

Design

Controlled clinical trial with parallel groups, single blind and randomized groups. The size of sample was 30 trauma patients.

Settings and conduct

This single blind randomized clinical trial study is performed on 30 trauma patients with mandibular fractures who referred to Shahid Rahnamun hospital in Yazd. Patient are randomly divided into two groups. In the intervention group, immediately after surgery, cinopar ampoule (Cinnagen company of Iran) is injected daily in addition to routine drugs. The control group receive only routine antibiotics and analgesics. Clinical caregiver is blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18-60 years, mandibular bone fractures which is needed surgery, open reduction and fixation. Exclusion criteria: Infection, patients with a history of fractures, patients taking corticosteroids , immunosuppressive drugs and digoxin. Calcium level greater than 10.

Intervention groups

In intervention group, patients receive cinopar ampoule (Cinnagen company) daily for one month (eight micrograms per kilogram, subcutaneous) in addition to routine drugs (antibiotics and analgesics). The control group receives only routine drugs including antibiotics and analgesics.

Main outcome variables

Bone healing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180507039576N1**

Registration date: **2021-06-18, 1400/03/28**

Registration timing: **registered_while_recruiting**

Last update: **2021-06-18, 1400/03/28**

Update count: **0**

Registration date

2021-06-18, 1400/03/28

Registrant information

Name

Alireza Navabazam

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2021-08-11, 1400/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of teriparatide (cinopar) on bone healing in mandibular fracture

Public title

Effect of cinopar in mandibular fracture

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

18-60 year Mandibular fracture Open reduction and internal fixation

Exclusion criteria:

Infection Patient with a history of fracture Patient taking immunosuppressive, corticosteroid and digoxin The level of calcium greater than 10

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly divided into two groups using random number table. This table is a set of numbers. Numbers 1 to 15 will be considered for the intervention group and numbers 16 to 30 for the control group. We will select one of the numbers and move in one of the directions, then the numbers will be recorded and assign to one of the groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the person who provided these drugs to patients had no information about the allocation of patients to intervention or control group.

Placebo

Not used

Assignment

Parallel

Other design features

In this study, 30 patients with mandibular fractures are randomly divided into two groups of 15 patients. Patients in the intervention group receive cinopar ampoule (8 micrograms per kilogram daily for one month) in addition to routine drug therapy and the control group only receive routine medication.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Sadoughi University of Medical Sciences

Street address

Campus of Medical Sciences, Shohadaye Gornam Blvd, Professor Hesabi Blvd

City

Yazd

Province

Yazd

Postal code

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Approval date

2021-03-13, 1399/12/23

Ethics committee reference number

IR.SSU.REC.1399.299

Health conditions studied

1

Description of health condition studied

Mandibular bone fracture

ICD-10 code

S02.60

ICD-10 code description

Fracture of mandible, unspecified

Primary outcomes

1

Description

Bone healing

Timepoint

Before surgery and one month after surgery.

Method of measurement

Evaluated both qualitatively, based on subjective fracture line changes , and quantitatively based on Hounsfield unit .

Secondary outcomes

1

Description

Pain

Timepoint

7, 14, 21, 28 days after surgery

Method of measurement

Visual Analogue Scale

2

Description

swelling

Timepoint

7, 14, 21, 28 days after surgery

Method of measurement

Examination

3

Description

Ecchymosis

Timepoint

7, 14, 21, 28 days after surgery

Method of measurement

Examination

4**Description**

Pus discharge

Timepoint

7, 14, 21, 28 days after surgery

Method of measurement

Examination

5**Description**

Dehiscence

Timepoint

7, 14, 21, 28 days after surgery

Method of measurement

Examination

Intervention groups**1****Description**

Intervention group: In this group, in addition to routine drug therapy, cinopar ampoule (8 micrograms per kilogram daily for one month) which is produced by Cinnagen company is injected subcutaneously in the area around the navel or arm.

Category

Rehabilitation

2**Description**

Control group: They receive only routine treatment, including antibiotics and analgesics

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Rahnamun hospital in Yazd

Full name of responsible person

Alireza Navab Azam

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Shahid Rahnamun hospital, Farokhi street, Yazd

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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

Yazd 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**

Yazd University of Medical Sciences

Full name of responsible person

Somayyeh Ebrahimi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry
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Person responsible for updating data

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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

Yes - There is 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

Total data

When the data will become available and for how long

Access time 6 months after the results are published

To whom data/document is available

All researchers

Under which criteria data/document could be used

Documentation and statistical analysis are made available to all researchers for larger research projects or other studies.

From where data/document is obtainable

Researcher email : Ebrahimi_6920@yahoo.com

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

Immediately after sending the request by email

Comments

If necessary, call the number: 00989151365961