Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 kilramog,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)

Phone
+98 35 3625 5881

Email address
alirezanavabazam266@gmail.com

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 Gomnam Blvd, Professor Hesabi Blvd
City
Yazd
Province
Yazd
Postal code
۸۹۱۵۱۷۳۱۴۹
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
Street address
Shahid Rahnamun hospital, Farokhi street,Yazd
City
Yazd
Province
Yazd
Postal code
8913814396
Phone
+98 35 3312 2002
Fax
+98 35 3312 3005
Email
Rahnamoon@ssu.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr.Masoud Mirzaii
Street address
Theird floor,Yazd University of Medical Science ,Bahonar Square,Yazd Town
City
Yazd
Province
Yazd
Postal code
۸۹۱۶۹۷۸۴۷۷
Phone
+98 35 3726 3733
Fax
+98 35 3726 3732
Email
dvc.research@ssu.ac.ir
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
Street address
No.301, Infont of Iraj Mirza Ave .,Moalem Blvd ., kashmar Town
City
Kashmar
Province
Razavi Khorasan
Postal code
۹۶۷۱۹۹۹۵۱۸
Phone
+98 51 8223 2306
Email
Ebrahimi_6920@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Alireza Navab Azam
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
No.41.,Fourth dead end., Golha alley., Shahid Beheshti Blvd.,Yazd Town
City
Yazd
Province
Yazd
Postal code
8916666596
Phone
+98 35 3626 0000
Email
Alirezanavabazam266@gmail.com

Person responsible for updating data

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
Street address
No.301 ,Infront of Iraj Mirza Ave , Moalem Blv .,Kashmar Town
City
Kashmar
Province
Razavi Khorasan
Postal code
9671999518
Phone
+98 51 8223 2306
Email
Ebrahimi_6920@yahoo.com

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