Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Effect of Calcitonin on Healing Duration and Pain Relief in Patients with Maxillofacial Fracture

Protocol summary

Study aim
The aim of this study is to investigate the effectiveness of Intranasal calcitonin in controlling pain due to maxillofacial fracture

Design
non randomized clinical trial with crossover control and trial groups with blinded participants.

Settings and conduct
Patients with maxillofacial fractures referring to Imam Reza hospital after receiving informed consent are included in this study. Participants in this study will be divided into two groups. Intervention group will receive 200 unit calcitonin nasal spray after surgery, and the control group will receive normal saline serum nasal spray. The severity of pain is then evaluated daily for up to seven days after the operation, with the severity of: no pain (0) to the most severe pain (10) using visual analog scale for pain. the daily dose of analgesic is also measured . The patient is allowed to request 250 mg of injectable acetaminophen each day up to a maximum daily dose of 4 g (maximum permissible dose) in the event of pain.

Participants/Inclusion and exclusion criteria
All patients with maxillofacial fracture which happened within less than a week will be included in the study. The patients with systemic conditions impairing wound healing, patients with mental illness history of allergy to calcitonin and calcium metabolism disorder are excluded

Intervention groups
Participant receive 200 unit of intranasal calcitonin

Main outcome variables
Postoperative pains intensity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190409043211N1**
Registration date: **2019-04-28, 1398/02/08**
Registration timing: **registered_while_recruiting**

Last update: **2019-04-28, 1398/02/08**
Update count: **0**

Registration date
2019-04-28, 1398/02/08

Registrant information

Name
Farzin Ahmadpour

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 3334 7054

Email address
phoenixinfire@ymail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-08, 1398/01/19

Expected recruitment end date
2019-06-09, 1398/03/19

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Calcitonin on Healing Duration and Pain Relief in Patients with Maxillofacial Fracture

Public title
Effect of Calcitonin on Pain Relief in Patients with Fractures

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients with maxillofacial fracture which happened within less than a week
Exclusion criteria:
Systemic conditions impairing wound healing Patient mental illness Allergy to calcitonin Calcium metabolism disorder
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **46**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
After completing a full description of how the study will be conducted to the participants and obtaining the informed consent and that the patients will be sure that they would not be deprived of routine therapy, during the study, participants will not know that they are going to receive placebo or intranasal calcitonin.
Placebo
Used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Central Building of Tabriz University of Medical Sciences, Daneshgah Street, Tabriz, Iran
City
Tabriz
Province
East Azarbaijan
Postal code
5166614711
Approval date
2019-04-07, 1398/01/18
Ethics committee reference number
IR.TBZMED.REC.1398.001

Health conditions studied

1

Description of health condition studied
mandibular fracture
ICD-10 code
S02.6
ICD-10 code description
Fracture of mandible

2

Description of health condition studied
maxillofacial fracture
ICD-10 code
S02.4
ICD-10 code description
Fracture of malar, maxillary and zygoma bones

Primary outcomes

1

Description
pain due to maxillofacial fracture
Timepoint
At 1، 2، 3، 4، 5، 6، and 7 day after drug
Method of measurement
Visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Single dose of intranasal calcitonin (200 unit)
Category
Treatment - Drugs

2

Description
Control group: intranasal NaCl spray
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center

Imam Reza Medical Research & Training Hospital

Full name of responsible person
Javad Yazdani

Street address
Imam Reza Medical Research & Training Hospital, Tabriz University of Medical Sciences, Golgasht Ave, Tabriz, IRAN

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Web page address
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Javad Yazdani

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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
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Farzin Ahmadpour

Position
Senior resident

Latest degree
Medical doctor

Other areas of specialty/work
Oral and maxillofacial surgeon

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is 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
Title and more details about the data/document
data can be shared anonymously
When the data will become available and for how long
Data will be available from 2019
To whom data/document is available
academic Researchers
Under which criteria data/document could be used
There are no specific conditions
From where data/document is obtainable
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What processes are involved for a request to access data/document
6 months
Comments