

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Aug 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,
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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