Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Long-acting local anesthetic infiltration in surgical wound for post operative pain control in zygomatico maxillary complex fracture

Protocol summary

Summary

Background and Objectives: Effective post- operative pain control is an important factor in reducing the incidence of morbidity and in promoting early mobilization and discharge from hospital. Wound infiltration with a local anesthetic for post- operative pain relief following surgery of zygomatico maxillary complex (Zmc) fracture, seems to be an attractive method because of its simplicity , safety and low cost. This study intends to determine if this method could reduce post operative pain and complications as well as the amount of post operative analgesics requirements. Design: Sixty patients with Zmc fracture who are candidate for open reduction with intra and extra oral approaches, will be recruited. Main inclusion criteria are patients under going open reduction with intra and extra oral approaches for(Zmc) fracture and main exclusion criteria are history of addiction , seizure and psychopathic conditions. After providing written consent form, they will be randomly divided into the two groups: study group will undergo infiltration of 10 ml bupivacaine at the site of incision while the control group will receive placebo.At the end of the study two groups will be compared in terms of pain and analgesic consumption at various times after operation. Inclusion: age from 20 to 60 people who are going to have open reduction for Zygomatic fracture Exclusion criteria : Addiction, Seizure, psychopathic conditions and refuse to participate.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201406201772N14**
Registration date: **2014-06-27, 1393/04/06**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-06-27, 1393/04/06

Registrant information

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Recruitment status

Recruitment complete

Funding source

Tabriz university of medical science/ Vice chancellor of reseach

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2015-03-18, 1393/12/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Long-acting local anesthetic infiltration in surgical wound for post operative pain control in zygomatico maxillary complex fracture

Public title

post operative pain control

Purpose

Prevention

Inclusion/Exclusion criteria
Inclusion: age from 20 to 60 people who are going to have open reduction for Zygomatic fracture Exclusion criteria : Addiction, Seizure, psychopathic conditions and refuse to participate.
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tabriz university of medical science ,fuculty of dentistry/ reseach ethical committee
Street address
Daneshghah street/ Tabriz university of medical science/fuculty of dentistry/ Vice chancellor of reseach/ ethical committee
City
Tabriz
Postal code
Approval date
2014-05-26, 1393/03/05
Ethics committee reference number
9338

Health conditions studied

1

Description of health condition studied
post operative pain control
ICD-10 code
T41.3
ICD-10 code description
local Anesthetic

Primary outcomes

1

Description
Pain
Timepoint
0, 2, 4, 6, 12 and 24 hours after operation
Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Opioid cosumption
Timepoint
0, 2, 4, 6, 12 and 24 hours after operation
Method of measurement
Total Dose

Intervention groups

1

Description
Surgical site infiltrated before wound closure with 10 ml Bupivacaine 0.5%
Category
Treatment - Drugs

2

Description
Surgical site infiltrated before wound closure with placebo
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital/Tabriz
Full name of responsible person
Dawood Aghamohammadi
Street address
Daneshghah street/ Imam Reza Hospital
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz university of medical science/ Vice chancellor

of reseach

Full name of responsible person
Dawood Aghamohammadi

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Daneshghah street/ Tabriz university of medical science/ Fuculty of medicin

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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 science/ Vice chancellor of reseach

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Tabriz university of medical science/fuculty of medicin/ Anesthesiology Dept

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty