

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 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

Name

Dawood Aghamohammadi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1381 8940

Email address

aghamohammadid@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz university of medical science/ Vice chancellor of research

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 consumption

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

Street address

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

City

Tabriz

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

Full name of responsible person

Dawood Aghamohammadi

Position

Associated Professor

Other areas of specialty/work

Street address

Daneshghah street/ Tabriz university of medical science//fuculty of medicin/ Anesthesiology Dept

City

Tabriz

Postal code

Phone

+98 41 1381 8940

Fax

Email

aghamohammadid@tbzmed.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz university of medical science/fuculty of

medicin/ Anesthesiology Dept

Full name of responsible person

Dawood Aghamohammadi

Position

Associated Professor

Other areas of specialty/work

Street address

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

City

Tabriz

Postal code

Phone

+98 41 1381 8940

Fax

Email

aghamohammadid@tbzmed.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tabriz university of medical science/fuculty of medicin/ Anesthesiology Dept

Full name of responsible person

Dawood Aghamohammadi

Position

Associated Professor

Other areas of specialty/work

Street address

Daneshghah street/ Tabriz university of medical science//fuculty of medicin/ Anesthesiology Dept

City

Tabriz

Postal code

Phone

+98 41 1381 8940

Fax

Email

aghamohammadid@tbzmed.ac.ir

Web page address

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