Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Investigation of Preoperative Oral Montelukast Prescription on Postoperative Pain Levels Following Zygomaticomaxillary Complex Fracture Surgery

Protocol summary

Study aim

The aim of this study is to evaluate the effectiveness of a specific analgesic protocol in patients undergoing surgery for zygomaticomaxillary complex (ZMC) fractures.

Design

A triple-blind, randomized controlled trial was conducted on 80 patients with ZMC fractures. Participants were randomly assigned to Montelukast and control groups (n=40 each), using a random numbers table. Each group was further divided into four subgroups (n=10) based on timing of drug administration (0, 6, 12, or 24 hours before surgery). Randomization and allocation concealment were performed using a random starting point in the table.

Settings and conduct

Randomization was performed using a random number table; patients, surgeons, and data analysts were blinded, while only the anesthesiologist and dental student preparing the medication were aware of group assignments.

Participants/Inclusion and exclusion criteria

Individuals aged 18 to 60 years, of either gender, with a body mass index of less than 30 kg/m² (non-obese), with ZMC fractures, who present to the maxillofacial surgery department of the hospital for treatment. Exclusion criteria include: preoperative use or dependence on narcotic substances, peptic ulcer disease, hepatic or renal dysfunction, psychiatric disorders, allergy to amide local anesthetics or opioids, and a history of seizures.

Intervention groups

The effect of a single preoperative oral dose of Montelukast (10 mg) on postoperative pain intensity in patients undergoing surgery for ZMC fractures. Eighty patients will be randomly assigned to four experimental and four control subgroups based on the timing of drug administration (0, 6, 12, or 24 hours before surgery).

Main outcome variables

Timing of montelukast administration before surgery, amount of analgesic consumption after surgery, and patient satisfaction with pain management.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250412065292N1**
Registration date: **2025-06-08, 1404/03/18**
Registration timing: **prospective**

Last update: **2025-06-08, 1404/03/18**
Update count: **0**

Registration date

2025-06-08, 1404/03/18

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-08-23, 1404/06/01

Expected recruitment end date

2026-08-22, 1405/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of Preoperative Oral Montelukast Prescription on Postoperative Pain Levels Following Zygomaticomaxillary Complex Fracture Surgery

Public title

Studying the effect of montelukast in reducing pain after surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The participating patients who have zygomaticomaxillary complex fracture Patients aged between 18 and 60 years Patients of both sexes, male and female Patients with a BMI of less than 30 kg/m² (non-obese)

Exclusion criteria:

Preoperative use or dependence on narcotic drugs Having peptic ulcer disease, hepatic or renal dysfunction, or psychiatric disorders Allergy to amide local anesthetics and narcotics, and a history of seizures Cases where the participant requires intensive care unit admission after surgery

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

To randomly allocate 80 patients into two groups (intervention and control, each with 40 patients) and subsequently divide each group into four time-based subgroups (0, 6, 12, and 24 hours before surgery), stratified block randomization will be employed. Patients will be stratified into four layers based on age (under 50 years and 50 years and older) and gender (male/female) to ensure balance in key variables. Within each stratum, patients will be evenly assigned to the intervention and control groups using block randomization (block size of 4) via the R software. Each group will then be randomly divided into four time-based subgroups (10 patients each). The random sequence will be generated using the `blockrand` function in R and documented with a specified seed. For allocation concealment, group and timing information will be placed in opaque, sealed envelopes managed by a student. These envelopes will be opened at enrollment to determine the group and timing of drug or placebo administration. The triple-blind design ensures that patients, treating surgeons, and data analysts remain unaware of the allocations.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, a triple-blind randomized allocation will be used. Although the randomization codes will be concealed from the patient, the treating surgeon, and the data analyst (triple-blind randomized clinical trial), the dental student and the anesthesiologist will be aware of the group to which the patient has been assigned. Patients will be blinded in the following way: before the surgery, each patient will be given a glass of juice and informed that, in this study, there are two groups receiving the juice—one group receives juice containing the medication, and the other receives juice without the medication. Only the researcher will know which juice contains the drug.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Biomedical Research Faculty of Dentistry Tabriz University of Medical Sciences

Street address

Faculty of Dentistry, Tabriz University of Medical Sciences, Golgasht St, University St

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Approval date

2024-11-10, 1403/08/20

Ethics committee reference number

IR.TBZMED.DENTISTRY.REC.1403.043

Health conditions studied

1

Description of health condition studied

Zygomaticomaxillary complex fracture

ICD-10 code

S02.40

ICD-10 code description
Fracture of malar, maxillary and zygoma bones, unspecified

Primary outcomes

1

Description
Postoperative pain intensity score measured using the Visual Analogue Scale from 0 to 10, in patients undergoing surgery for zygomaticomaxillary complex fractures, comparing Montelukast and control groups.
Timepoint
Pain intensity will be assessed immediately after recovery and every two hours for a total duration of 12 hours.
Method of measurement
The outcome was measured using the Visual Analogue Scale for pain intensity.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: At time intervals of 0, 6, 12, and 24 hours before transfer to the operating room, patients will receive a 40 mL glass of fruit juice containing 10 mg of montelukast (Abidi Pharmaceuticals) dissolved in it.
Category
Prevention

2

Description
Control group: At different time intervals — 0, 6, 12, and 24 hours before being transferred to the operating room, patients will be given a glass of drug-free fruit juice.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Farokh Farhadi Shabestari
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Sponsors / Funding sources

1

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Name of organization / entity
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Web page address
https://researchvice.tbzmed.ac.ir/?PageID=497
Grant name
Grant code / Reference number
73581
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
Farokh Farhadi Shabestari

Position
Associate Professor
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Person responsible for scientific inquiries

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Person responsible for updating data

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https://dentistryfac.tbzmed.ac.ir/uploads/User/32/jarahi/CV%20dr%20farhadi.pdf

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
No - There is not a plan to make this available
Clinical Study Report
Yes - There is 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
Not applicable
Title and more details about the data/document
The shared IPD will include deidentified data related to primary outcome measures, such as Visual Analogue Scale scores recorded every 2 hours for 12 hours postoperatively, timing of drug administration, and demographic variables (age, sex, BMI). These data will be shared upon reasonable request after publication of the main results.
When the data will become available and for how long
The deidentified data and related documents will be available starting 6 months after publication of the study results and will remain accessible for a period of 2 years following that date.
To whom data/document is available
Deidentified individual participant data and supporting documents will be shared with qualified researchers

affiliated with academic institutions. Access may also be granted to researchers from non-academic organizations, such as industry or healthcare companies, upon reasonable request and subject to approval by the principal investigator.

Under which criteria data/document could be used

Deidentified individual participant data and supporting documents will be shared only for research purposes, such as meta-analyses, secondary analyses of outcomes, or validation of findings. Requests for data access must include a detailed research proposal and will be reviewed by the principal investigator and an independent data access committee to ensure ethical use and scientific validity. Approved data will be shared via secure email or institutional data-sharing platforms under a data use agreement.

From where data/document is obtainable

Applicants seeking access to the deidentified individual participant data and related documents should contact the principal investigator via the following communication channels: Preferred contact method: Email Email address: drfarrokhfarhadi@gmail.com Postal address: Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Tabriz University of Medical Sciences, Golgasht Street, Tabriz, Iran Phone number: +989144138028 Fax number: +984133346977 Contact person: Dr. Farokh Farhadi Shabestari, Principal Investigator

What processes are involved for a request to access data/document

To request access to the deidentified individual participant data and related documents, applicants must follow these steps: 1. Submit a Request: Send an email to the principal investigator (Dr. Farokh Farhadi Shabestari at drfarrokhfarhadi@gmail.com, including the following: * A detailed research proposal outlining the objectives and intended analyses. * A description of how the data will be used and stored. * Institutional affiliation and ethical approval (if applicable). 2. Review Process: The research team will review requests within 2 to 4 weeks. The review will evaluate: * Scientific merit and relevance of the proposed project. * Ethical considerations and data security measures. * Compatibility with the original study’s consent and ethical approval. 3. Data Use Agreement: Approved applicants will be required to sign a Data Use Agreement (DUA) to ensure the responsible use of shared data and prevent attempts to reidentify participants. 4. Data Delivery: Upon signing the DUA, data will be shared securely via encrypted email or institutional file-sharing platforms within 1 week. Estimated total time: Approximately 3 to 5 weeks from initial request to receipt of data.

Comments