Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of melatonin on postoperative pain and sensory recovery following zygomaticomaxillary complex fractures

Protocol summary

Study aim

To determine whether melatonin reduces postoperative pain and improves sensory recovery in patients undergoing surgical fixation of zygomaticomaxillary complex (ZMC) fractures.

Design

Randomised Controlled Trial

Settings and conduct

A randomized controlled trial of 60 ZMC fracture patients will be conducted at AFID, CMH Rawalpindi over six months. Patients will be randomized 1:1 to melatonin 10 mg or placebo for 15 days, starting 60–90 minutes preoperatively. All will undergo three-point ORIF and standardized postoperative care. Pain and sensory recovery will be assessed on day 7 by VAS and pin-prick testing using a blinded assessor.

Participants/Inclusion and exclusion criteria

Inclusion Criteria * Patients aged 18–60 years. * Male or female patients. * Patients diagnosed with zygomaticomaxillary complex (ZMC) fractures involving the infra orbital foramen. * Patients planned for open reduction and internal fixation of the ZMC fracture. * Patients willing to participate and provide informed consent. Exclusion Criteria * Patients with concomitant fractures of other parts of the maxillofacial skeleton. * Pregnant women. * Patients taking anxiolytic medications. * Patients taking antidiabetic medications. * Patients unwilling to provide informed consent.

Intervention groups

There are 2 intervention groups in this study: Melatonin group (Group A): 10 mg oral melatonin at bedtime for 15 days, starting 60–90 minutes before surgery. Placebo group (Group B): 10 mg placebo at bedtime for 15 days, starting 60–90 minutes before surgery. Allocation: 30 participants in each group, with a total sample size of 60.

Main outcome variables

The main outcome variables of this study are: Postoperative pain — measured using the Visual Analogue Scale (VAS) on postoperative day 7. Sensory recovery — assessed using the pin-prick test and recorded on a 0–10 VAS scale on postoperative day 7.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260813070637N1**
Registration date: **2026-10-01, 1405/07/09**
Registration timing: **prospective**

Last update: **2026-10-01, 1405/07/09**
Update count: **0**

Registration date

2026-10-01, 1405/07/09

Registrant information

Name

Rana Khan

Name of organization / entity

Armed Forces Institute of Dentistry, Rawalpindi

Country

Pakistan

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Email address

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Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2027-01-01, 1405/10/11

Expected recruitment end date

2027-06-30, 1406/04/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of melatonin on postoperative pain and sensory recovery following zygomaticomaxillary complex fractures

Public title

Effect of Melatonin on Pain and Facial Sensation After Surgery for Cheekbone Fractures

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients between 18–60 years Either male or female gender Cases of complex zygomaticomaxillary fractures involving infra orbital foramen Cases planned for surgery i.e open reduction and internal fixation

Exclusion criteria:

Concomitant fracture of the maxillofacial skeleton Pregnant women Patients on anxiolytics or antidiabetics

Age

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

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomly allocated in a 1:1 ratio to either the melatonin group (Group A) or placebo group (Group B) using a lottery method. Treatment assignments will be placed in sequentially prepared, sealed opaque envelopes to ensure allocation concealment.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants will be blinded to treatment allocation. Melatonin and placebo tablets will be identical in appearance and will be administered in the same manner (10 mg orally at bedtime), with both groups receiving treatment for 15 days. The principal investigator and surgeon performing the zygomaticomaxillary complex fracture fixation will not be involved in allocation concealment or postoperative outcome assessment. Treatment allocation will be performed by lottery using sealed opaque envelopes. The treating surgeon and healthcare providers involved in routine preoperative care will not be informed of the treatment allocation unless knowledge is required for patient safety. The outcome assessor (dentist performing the visual analogue scale assessment and pin-prick sensory testing on postoperative day 7) will be blinded to treatment allocation. The assessor will not have access to the randomisation record or medication assignment. Data analysis will be performed using coded groups (e.g., Group A and Group B) so that the statistician/data analyst is unaware of which group received melatonin until the primary analysis is completed. The treatment code will be revealed after completion of the analysis. The study does not involve a separate Data Safety and Monitoring Board. Manuscript writers will use coded group data and will remain unaware of the treatment identity during preparation of the initial analysis and manuscript, where feasible. Thus, the study will use concealed allocation with blinded participants, outcome assessor, and data analyst, while the operating surgeon and routine healthcare providers will not participate in outcome assessment.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Armed Forces Institute of Dentistry Rawalpindi

Street address

Armed Forces Institute of Dentistry, CMH Rawalpindi

City

Rawalpindi

Postal code

46000

Approval date

2025-09-03, 1404/06/12

Ethics committee reference number

918/Trg/Sep/2025

Health conditions studied

1

Description of health condition studied

Zygomaticomaxillary complex fractures with infraorbital nerve sensory disturbance and postoperative pain

ICD-10 code

S02.40

ICD-10 code description

Fracture of malar, maxillary and zygoma bones, unspecified

Primary outcomes

1

Description
Postoperative pain
Timepoint
Postoperative day 7
Method of measurement
VAS (0–10)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Melatonin 10 mg orally at bedtime for 15 days, starting 60–90 minutes before surgery
Category
Treatment - Drugs

2

Description
Control group: Placebo 10 mg orally at bedtime for 15 days, starting 60–90 minutes before surgery
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Armed Forces Institute of Dentistry
Full name of responsible person
Rana Talha Ahmad Khan
Street address
Combined Military Hospital, Rawalpindi cantt, Rawalpindi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
National University of Medical Sciences Pakistan
Full name of responsible person
Dr Saad Mahmood
Street address
Askari 14 Rawalpindi Cantt area
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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
National University of Medical Sciences Pakistan
Proportion provided by this source
100
Public or private sector
Private
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
Armed Forces Institute of Dentistry, Rawalpindi
Full name of responsible person
Rana Talha Ahmad Khan
Position
Specialty Registrar
Latest degree
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Person responsible for scientific inquiries

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Full name of responsible person

Dr Saad Mehmood

Position

Classified Specialist in Oral & Maxillofacial Surgery

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Armed Forces Institute of Dentistry, Rawalpindi

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Position

Specialty Registrar

Latest degree

Bachelor

Other areas of specialty/work

Dentistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The study involves a relatively small participant population and sharing individual level data may pose a risk of participant re identification despite de identification

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Study Data Dictionary – Effects of Melatonin on Postoperative Pain and Sensory Recovery Following Zygomaticomaxillary Complex Fracture Surgery. The data dictionary will include definitions, descriptions, coding, formats, and labels for the variables collected in the study, including demographic characteristics, treatment allocation, postoperative pain scores, sensory recovery assessments, and relevant clinical and surgical variables. No directly identifying participant information will be included.

When the data will become available and for how long

The data dictionary will be made available after publication of the study results and will remain available for a period of 5 years there after

To whom data/document is available

The data dictionary will be available to qualified academic researchers and other researchers upon reasonable request, subject to institutional policies and applicable ethical and confidentiality requirements.

Under which criteria data/document could be used

Access will be provided for legitimate scientific and research purposes. Requests will be reviewed to ensure that the proposed use is consistent with the study objectives, ethical requirements, and protection of participant confidentiality.

From where data/document is obtainable

The data dictionary will be available upon request from the study investigators through the corresponding author’s institutional email address. Requests should include the applicants name , institutional affiliation, contact information, and intended research purpose

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

Researchers may submit an access request to the study investigators via the corresponding author. Requests will be reviewed for scientific and ethical appropriateness, and approved applicants will be provided with the relevant data dictionary electronically, subject to applicable institutional policies and confidentiality requirements.

Comments