Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Comparative Efficacy of Dexamethasone Versus Prednisone in the Prevention of Post-Operative Edema, Pain, and Trismus Following Mandibular Third Molar Surgery

Protocol summary

Study aim
To compare the effectiveness of preoperatively administered dexamethasone (8 mg intramuscular) against prednisone (40 mg oral) in reducing postoperative edema, pain intensity, and trismus severity following impacted mandibular third molar extraction

Design
retrospective, double-blind, parallel-group randomized controlled trial

Settings and conduct
Dept of Oral and Maxillofacial Surgery, Islam Dental College, Sialkot.

Participants/Inclusion and exclusion criteria
Patients were eligible for inclusion if they were aged 18–40 years, had a unilateral impacted mandibular third molar requiring surgical extraction under local anaesthesia, and were classified as American Society of Anesthesiologists (ASA) Physical Status Class I or II. The molar had to be classified as Class II Position B impaction on panoramic radiography (Pell and Gregory classification). Exclusion criteria encompassed active systemic illness (diabetes mellitus, hypertension, renal or hepatic disease), known hypersensitivity or contraindication to corticosteroids, current use of systemic corticosteroids or non-steroidal anti-inflammatory drugs, pregnant or lactating women, active pericoronitis or acute pericoronal infection at the surgical site, active peptic ulcer disease, immunocompromised status, and tobacco or alcohol use disorder. Patients who required general anaesthesia or sedation were also excluded

Intervention groups
Group A: Dexamethasone 8 mg administered locally into pterygomandibular 20 minutes before surgical extraction, plus an oral placebo capsule identical in appearance to the prednisone capsule. Group B : Patients received prednisone 40 mg orally 60 minutes before surgery, plus an intramuscular injection of normal saline (0.9% NaCl, 2 mL) in an identical syringe to maintain blinding.

Main outcome variables
Primary: facial edema at Day 2, Day 5, Day 7 Secondary: VAS pain score (0–10), trismus

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230714058773N5**
Registration date: **2026-07-30, 1405/05/08**
Registration timing: **retrospective**

Last update: **2026-07-30, 1405/05/08**
Update count: **0**

Registration date
2026-07-30, 1405/05/08

Registrant information

Name
Tehmina Maryam

Name of organization / entity
Armed forces institute of dentistry, combined military hospital, Rawalpindi, Pakistan

Country
Pakistan

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+92 333 9576737

Email address
tehminamaryam@hotmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-01-02, 1404/10/12
Expected recruitment end date
2026-07-02, 1405/04/11
Actual recruitment start date
2026-07-02, 1405/04/11
Actual recruitment end date
2026-07-02, 1405/04/11
Trial completion date
2026-07-02, 1405/04/11

Scientific title
Comparative Efficacy of Dexamethasone Versus Prednisone in the Prevention of Post-Operative Edema, Pain, and Trismus Following Mandibular Third Molar Surgery

Public title
Comparative Efficacy of Dexamethasone Versus Prednisone in the Prevention of Post-Operative Edema, Pain, and Trismus Following Mandibular Third Molar Surgery
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients were eligible for inclusion if they were aged 18–40 years, had a unilateral impacted mandibular third molar requiring surgical extraction under local anaesthesia, and were classified as American Society of Anesthesiologists (ASA) Physical Status Class I or II. The molar had to be classified as Class II Position B impaction on panoramic radiography (Pell and Gregory classification).
Exclusion criteria:
Exclusion criteria encompassed active systemic illness (diabetes mellitus, hypertension, renal or hepatic disease), known hypersensitivity or contraindication to corticosteroids, current use of systemic corticosteroids or non-steroidal anti-inflammatory drugs, pregnant or lactating women, active pericoronitis or acute pericoronal infection at the surgical site, active peptic ulcer disease, immunocompromised status, and tobacco or alcohol use disorder. Patients who required general anaesthesia or sedation were also excluded
Age
From **18 years** old to **40 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **80**
Actual sample size reached: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible participants were randomized in a 1:1 ratio using a computer-generated random number sequence (www.randomizer.org), with allocation concealment maintained through sequentially numbered, opaque, sealed envelopes prepared by an independent statistician not involved in patient care or outcome assessment
Blinding (investigator's opinion)
Double blinded
Blinding description
Eligible participants were randomized in a 1:1 ratio using a computer-generated random number sequence (www.randomizer.org), with allocation concealment maintained through sequentially numbered, opaque, sealed envelopes prepared by an independent statistician not involved in patient care or outcome assessment
Placebo
Used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Department of Oral and Maxillofacial Surgery, Islam Dental College, Sialkot, Pakistan
Street address
Islam Medical And Dental College, Pasrur road, sialkot, Pakistan
City
Sialkot
Postal code
51310
Approval date
2026-02-02, 1404/11/13
Ethics committee reference number
IMDC/IREC/2026/047

Health conditions studied

1

Description of health condition studied
Impacted mandibular third molar
ICD-10 code
K08.3
ICD-10 code description
Retained dental root

Primary outcomes

1

Description

facial edema

Timepoint

at day 2, day 5, day 7

Method of measurement

sum of 3 linear measurements

Secondary outcomes

1

Description

Primary: facial edema at baseline,

Timepoint

Day 2, Day 5, Day 7

Method of measurement

sum of 3 linear measurements

2

Description

Secondary: VAS pain score (0–10), trismus , and adverse events (nausea/vomiting, hyperglycemia, insomnia, dry socket)

Timepoint

immediately after, at day 2 and day 5 and 7

Method of measurement

visual analog scale, reduction in maximum interincisal distance from baseline

Intervention groups

1

Description

Intervention group: Patients received dexamethasone 8 mg administered locally into pterygomandibular 20 minutes prior to the commencement of surgical extraction, plus an oral placebo capsule identical in appearance to the prednisone capsule

Category

Other

2

Description

Intervention group: Group B (Prednisone): 40 mg oral, 60 minutes pre-op, plus an intramasseteric normal saline injection

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Oral and Maxillofacial Surgery, Islam Dental College, Sialkot, Pakistan

Full name of responsible person

Dr Salman Ahmad

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Islam Medical And Dental College, Pasrur road, sialkot, Pakistan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Department of Oral and Maxillofacial Surgery, Islam Dental College, Sialkot

Full name of responsible person

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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

Department of Oral and Maxillofacial Surgery, Islam Dental College, Sialkot

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

Department of Oral and Maxillofacial Surgery, Islam Dental College, Sialkot

Full name of responsible person

Dr Tehmina Maryam

Position

CONSULTANT

Latest degree
Specialist
Other areas of specialty/work
Oral and maxillofacial surgery
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Person responsible for scientific inquiries

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Latest degree
Specialist
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not 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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Comparative Efficacy of Dexamethasone Versus Prednisone in the Prevention of Post-Operative Edema, Pain, and Trismus Following Mandibular Third Molar Surgery
When the data will become available and for how long
for good after the publication
To whom data/document is available
Dr Tehmina Maryam
Under which criteria data/document could be used
Data will be shared with researchers who provide a scientifically sound proposal for a purpose consistent with participant consent and IRB approval, subject to a data access agreement and no attempt at re-identification.
From where data/document is obtainable
tehminamaryam27@gmail.com
What processes are involved for a request to access data/document
Data will be shared with researchers who submit a written request to the corresponding author, including a scientifically sound proposal; requests will be reviewed for consistency with participant consent and IRB approval, and a data access/use agreement will be signed before de-identified data are released.
Comments