

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 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

Phone

+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
Street address

Islam Medical And Dental College, Pasrur road, sialkot, Pakistan
City
Sialkot
Postal code
51310
Phone
+92 333 9576737
Email
tehminamaryam27@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Department of Oral and Maxillofacial Surgery, Islam Dental College, Sialkot
Full name of responsible person
Tehmina Maryam
Street address
Islam Medical And Dental College, Pasrur road, sialkot, Pakistan
City
Sialkot
Postal code
51310
Phone
+92 333 9576737
Email
tehminamaryam27@gmail.com
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

Street address

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

City

Sialkot

Province

punjab

Postal code

51310

Phone

+98 33 3957 6737

Email

tehminamaryam27@gmail.com

Other areas of specialty/work

Oral and maxillofacial surgery

Street address

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

City

Sialkot

Province

punjab

Postal code

51310

Phone

+98 33 3957 6737

Email

tehminamaryam27@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

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

Full name of responsible person

Noman

Position

consultant

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

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

City

Sialkot

Province

Punjab

Postal code

51310

Phone

+98 33 3957 6737

Fax**Email**

tehminamaryam27@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

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

Full name of responsible person

Dr Salman Ahmad

Position

Assistant Professor

Latest degree

Specialist

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