Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of Premedication with Ibuprofen and Dexamethasone on Success Rate of Inferior Alveolar Nerve Block for Teeth with Irreversible Pulpitis: A Randomized Clinical Trial

Protocol summary

Study aim
The aim of this study is to compare the effectiveness of Ibuprofen and Dexamethasone in reduction of frequency of pain after giving inferior alveolar nerve block to teeth with irreversible pulpitis.

Design
Randomized Controlled Trial

Settings and conduct
The study conducted at the Operative Dentistry department of Watim Dental College and Hospital.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Patients with pain VAS≥6 in mandibular molar having irreversible pulpitis 2. Patients who are not taking any antibiotics, anti-inflammatory or analgesics for at least one-week prior treatment 3. Patients between the ages 18-60 years 4. Both males and females Exclusion criteria: 1. Patients with any known allergies 2. Patients with a history of active peptic ulcer 3. Patients with osteoporosis 4. Pregnant or breast-feeding females 5. Patients with immunosuppression

Intervention groups
The patients were divided into two groups according to the selection used for medication: Group A received Ibuprofen 400 mg or Group B received Dexamethasone 0.5mg, with 30 patients in each group.

Main outcome variables
The patient was asked to rate their pain according to the Heft Parker visual analogue scale. The degree to which the drug was successful in minimizing pain (VAS≤54) within four hours of treatment was deemed effective.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240830062905N1**
Registration date: **2024-09-23, 1403/07/02**
Registration timing: **retrospective**

Last update: **2024-09-23, 1403/07/02**
Update count: **0**

Registration date
2024-09-23, 1403/07/02

Registrant information

Name
Hafsa Khalil

Name of organization / entity
Smart Consultancy for clinical research

Country
Pakistan

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+92 334 1101305

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-01, 1402/03/11

Expected recruitment end date
2023-10-30, 1402/08/08

Actual recruitment start date
2023-06-15, 1402/03/25

Actual recruitment end date
2023-12-01, 1402/09/10

Trial completion date
2024-01-17, 1402/10/27

Scientific title
Effect of Premedication with Ibuprofen and Dexamethasone on Success Rate of Inferior Alveolar Nerve Block for Teeth with Irreversible Pulpitis: A

Randomized Clinical Trial

Public title
Effect of Premedication with Ibuprofen and Dexamethasone on Success Rate of Inferior Alveolar Nerve Block for Teeth with Irreversible Pulpitis: A Randomized Clinical Trial

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
patients with pain (VAS≥114) in mandibular molar having irreversible pulpitis confirmed by cold test using ethyl chloride, patients who were not taking any antibiotics, anti-inflammatory or analgesics for at least one-week prior to treatment. Both males and females were included age 18-60 years.

Exclusion criteria:
1. Patients with any known allergies Patients with a history of active peptic ulcer Patients with osteoporosis Pregnant or breast-feeding females Patients with immunosuppression

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
A total of 60 patients requiring treatment for irreversible pulpitis were randomly assigned into two groups : Ibuprofen 400 mg or Dexamethasone 0.5mg (30 patients in each group). Patients were allocated to the medication group randomly using computer generated random number table. Aside from the case selection, all the clinical procedures were executed by a single endodontist (who was not part of the study process) and had no involvement with the study outcome.

Blinding (investigator's opinion)
Double blinded

Blinding description
To ensure blinding, neither the patient nor the operator had knowledge about the medication used as all medications were removed from their original containers and placed in new ones. In addition, allocation sequence was concealed from researchers who were part of the study to reduce bias. The patients were divided into two groups according to the selection used for medication: Group A (Ibuprofen 400 mg) or Group B (Dexamethasone 0.5mg), with 30 patients in each group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethical committee of Watim medical and dental college

Street address
Watim medical and dental college, main G.T road, Near T-chowk, Rawat Pakistan

City
Rawalpindi

Postal code
46000

Approval date
2023-05-03, 1402/02/13

Ethics committee reference number
WM&DCR/R&D (ERB)/2023/35

Health conditions studied

1

Description of health condition studied
Patients with irreversible pulpitis

ICD-10 code
K04.0

ICD-10 code description
Pulpitis

Primary outcomes

1

Description
Pain reduction

Timepoint
before and after 4 hours after the treatment

Method of measurement
Analogue Pain scale (VAS≤3) with scoring 1-10

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group-1: Dexamethasone with single dose of 0.5mg was given orally one hour prior to Inferior alveolar nerve block injections (IANB)

Category
Treatment - Drugs

2

Description
Intervention group-2: Ibuprofen with single dose of 400 mg was given orally one hour prior to Inferior alveolar nerve block injections (IANB)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Watim Medical and Dental College, Rawalpindi
Full name of responsible person
Sadaf Amjad
Street address
H no. 520, St#17, Sector-III, Airport housing society, Rawalpindi Pakistan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Watim Medical and Dental College
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
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Watim Medical and Dental College, Rawalpindi
Full name of responsible person
Sadaf Amjad
Position
Consultant
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Person responsible for updating data

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Position
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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
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available