

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 $VAS \geq 6$ 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 ($VAS \leq 54$) 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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sadafamjad@watim.com.pk

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 ($VAS \geq 114$) 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 ($VAS \leq 3$) 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

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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

Latest degree

Medical doctor

Other areas of specialty/work

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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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