

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 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

###### Phone

+92 334 1101305

###### Email address

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

**Street address**

H no. 520, St#17, Sector-III, Airport housing society, Rawalpindi Pakistan

**City**

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**Postal code**

46000

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**Email**

hafsakhalil100@gmail.com

**Sponsors / Funding sources**1**Sponsor****Name of organization / entity**

Watim Medical and Dental College

**Full name of responsible person**

Sadaf Amjad

**Street address**

Watim Medical and Dental College, main G.T road, Rawat

**City**

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sadafamjad986@gmail.com

**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**

Dentistry

**Street address**

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**City**

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**Province**

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## Person responsible for updating data

### Contact

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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