Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of Premedication of Ibuprofen and Dexamethasone on the Success of Inferior Alveolar Nerve Block for Teeth with Irreversible Pulpitis

Protocol summary

Summary

The aim of this study is evaluation of the effect of premedication with Iboprofen and Dexamethasone on the success rate of inferior alveolar nerve block. The patients are over eighteen years old, with irreversible pulpitis in one of the mandibular molars. Aggarwal's study is used to determine the volume of the subjects which consisted of 165 patients. Some of the inclusion criteria are patients over 18 with irreversible pulpitis in one of the mandibular molars with normal radiographic view. Some of the exclusion criteria are existence of systemic diseases, allergy to Lidocaine with 1/80000 Epinephrine and widening of periodontal ligament. All the patients take a capsule 30 minutes before anesthesia. The capsules contain Placebo (Lactose) or 400 mg Iboprophen or 0.5 mg Dexamethasone. Then inferior alveolar nerve is blocked. After fifteen minutes, signs of soft tissue anesthesia will be evaluated. If the patient have no signs of anesthesia (s)he is excluded from the study. In patients with successful nerve block cold test and electric pulpal test will be carried out and pain scores are evaluated with VAS. The tooth will be isolated and access cavity will be prepared. If the patient has pain during access cavity preparation, pain during pulp chamber entrance or pulp canal entrance, pain will be measured with VAS. No pain or mild pain will be considered as success and other pain intensities as failure.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011085141N1**
Registration date: **2012-04-02, 1391/01/14**
Registration timing: **na**

Last update:
Update count: **0**

Registration date

2012-04-02, 1391/01/14

Registrant information

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Recruitment status

Not enough for processing

Funding source

Periodontal and dental research center, Tabriz university of medical sciences

Expected recruitment start date

2012-03-15, 1390/12/25

Expected recruitment end date

2011-09-21, 1390/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Premedication of Ibuprofen and Dexamethasone on the Success of Inferior Alveolar Nerve Block for Teeth with Irreversible Pulpitis

Public title

Effect of Ibuprofen, dexamethasone and placebo on lower jaw nerve anesthesia

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: healthy patients having a first or second mandibular molar tooth with irreversible pulpitis and normal periapical radiographic appearance. Exclusion criteria: the presence of systemic disorders, a sensitivity to lidocaine with 1:80,000 epinephrine; a sensitivity to NSAIDs; nasal polyp; a history of gastrointestinal ulcers; the presence of widening of the periodontal ligament space; the presence of a periapical radiolucency; lactation, pregnancy; using any type of analgesic medication in the preceding 12 hours before the treatment; having a tooth not suitable for restoration, and having a full crown.

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **210**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics comitte of Tabriz university of medical sciences

Street address

Tabriz university of medical sciences

City

Tabriz

Postal code

Approval date

2012-01-18, 1390/10/28

Ethics committee reference number

9072

Health conditions studied

1

Description of health condition studied

Irreversiblae pulpitis

ICD-10 code

K04

ICD-10 code description

Diseases of pulp and periapical tissues

Primary outcomes

1

Description

inferior alveolar nerve block

Timepoint

45 minute after intervention (15 minute after injection)

Method of measurement

visual analoge scale

Secondary outcomes

1

Description

Analgesia during access cavity preparation and entrance into the root canal

Timepoint

during access cavity preparation and entrance into the root canal

Method of measurement

visual analoge scale

Intervention groups

1

Description

intervention group (Dexamethasone) 0.5 mg 30 min before injection

Category

Treatment - Drugs

2

Description

intervention groups (Ibuprofen) 400 mg 30 min before injection

Category

Treatment - Drugs

3

Description

control group (placebo: Lactose) 30 min before injection

Category

Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of dentistry
Full name of responsible person
Street address
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Periodontal and dental research center
Full name of responsible person
Prof. Reza Pourabbas
Street address
Faculty of dentistry
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Periodontal and dental research center
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty