Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 2026

The efficacy comparison of Ibuprofen, Gelofen, and Acetaminophen premedication on the depth of anesthesia during treatment of mandibular molar teeth with irreversible pulpitis

Protocol summary

Summary

The objective of this research was to compare the efficacy of premedication with Ibuprofen, Gelofen, or Acetaminophen on the depth of anesthesia during the treatment of teeth with irreversible pulpitis. This double-blind, randomized controlled clinical trial was done in 60 patients diagnosed with irreversible pulpitis in a mandibular tooth requiring Root Canal Therapy (RCT). Patients indicated their pain scores on a 10-point visual analogue scale (VAS), after which they were randomly divided into 4 groups (n=15). The subjects received identical capsules containing 400 mg Ibuprofen, or 400 mg Gelofen, or 325 mg Acetaminophen, or 500 mg Gloucose powder (placebo), 30 minutes before administration of inferior alveolar nerve block (IANB) with 2% lidocaine containing 1:80000 epinephrine. Lower lip and tongue tip numbness was assessed after 10 minutes, following which the teeth were tested with an electric pulp tester (EPT) and cold spray and their responses (negative or positive) were recorded. Access cavities were then prepared and the intensity of pain was scored based on VAS before the procedure, during access into the dentin, and when the pulp was exposed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201010094890N1**
Registration date: **2012-12-15, 1391/09/25**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-12-15, 1391/09/25

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Research deputy, Babol University of Medical Sciences

Expected recruitment start date

2010-05-08, 1389/02/18

Expected recruitment end date

2011-05-08, 1390/02/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy comparison of Ibuprofen, Gelofen, and Acetaminophen premedication on the depth of anesthesia during treatment of mandibular molar teeth with irreversible pulpitis

Public title

Effect of premedication on the depth of anesthesia during treatment of teeth diagnosed with irreversible pulpitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with the signs and symptoms of irreversible pulpitis in a mandibular molar tooth. Exclusion criteria: presence of any systemic diseases; consumption of any analgesics for at least 12 hours before enrollment in the study; presence of any contraindication to take Ibuprofen , Gelfen, Acetaminophen or 2% lidocaine with 1:800,00 epinephrine, or injection teqniques; teeth with extended restorations; previous endodontic treatment; advanced periodontal disease and periapical Radiolucency.

Age

From **14 years** old to **55 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Babol University of Medical sciences

Street address

Ganj Afrooz ave.

City

Babol

Postal code

Approval date

2010-04-12, 1389/01/23

Ethics committee reference number

1664

Health conditions studied

1

Description of health condition studied

Irriversible pulpitis

ICD-10 code

K04.0

ICD-10 code description

Irriversible pulpitis

Primary outcomes

1

Description

intensity of pain

Timepoint

before endodontic procedure, during access into dentin, when entering the pulp chamber

Method of measurement

Visual Analog Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Capsule contains Ibuprophen (400 mg), 30 minutes before anestesia delivery

Category

Treatment - Drugs

2

Description

Capsule contains gelofen (400 mg), 30 minutes before anestesia delivery

Category

Treatment - Drugs

3

Description

Capsule contains Acetaminophen (325 mg), 30 minutes before anestesia delivery

Category

Treatment - Drugs

4

Description

Control Capsule(contains 500 mg Gloucose), 30 minutes before anestesia delivery

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

dentistry faculty, university of medical sciences

Full name of responsible person
Street address
City
Babol

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research deputy of Babol University of Medcial Sciences
Full name of responsible person
Dr. Vahid Abbasi
Street address
Dentistry school, Ganj Afrooz Ave.
City
Babol
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research deputy of Babol University of Medcial Sciences
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

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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