

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 Glucose 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 techniques; 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
 Irrversible pulpitis

ICD-10 code

K04.0

ICD-10 code description

Irrversible 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 anesthesia delivery

Category

Treatment - Drugs

2

Description

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

Category

Treatment - Drugs

3

Description

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

Category

Treatment - Drugs

4

Description

Control Capsule(contains 500 mg Glucose), 30 minutes before anesthesia 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 Medical Sciences
Full name of responsible person
Dr. Vahid Abbasi
Street address
Dentistry school, Ganj Afroz 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 Medical 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

Contact

Name of organization / entity
Babol university of Medical Sciences
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Assistant Professor, Endodontist
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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