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

Country
Iran (Islamic Republic of)
Phone
+98 11 1220 0403
Email address
z.madani@mubabol.ac.ir

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, Gelofen, 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
Irreversible pulpitis
ICD-10 code
K04.0
ICD-10 code description
Irreversible 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 ibuprofen (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 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
empty

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Babol university of Medcial Sciences

Full name of responsible person
Dr. ZahraSadat Madani

Position
Assistant Professor, Endodontist

Other areas of specialty/work

Street address
dentistry school, Babol university of Medcial Sciences,Ganj Arooz ave.

City
Babol

Postal code

Phone
+98 11 1229 1409

Fax

Email
z.madani@mubabol.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Babol university of Medcial Sciences

Full name of responsible person
Dr. ZahraSadat Madani

Position
Assistant professor, Endodontist

Other areas of specialty/work

Street address
Dentistry School, Babol university of Medcial Sciences, Ganj Afrooz Ave.

City
Babol

Postal code

Phone
+98 11 1229 1408

Fax

Email
z.madani@mubabol.ac.ir

Web page address

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