

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Comparison of analgesic effect - the combination of acetaminophen and ibuprofen in the presence and absence of caffeine on pain after root canal treatment

Protocol summary

Summary

Pain following the root canal treatment is an important problem for the patients and dentists. Caffeine is an alkaloid that used with other analgesic to increase their effects. The goal of this study was comparing the analgesic effect of Acetaminophen & Ibuprofen combination in the presence and absence of Caffeine after root canal treatment. In this study, 45 patients that referred to the root canal treatment ward of Babol Dental College had been studied. The inclusion criteria: patients who need to treat one of their molar teeth with spontaneous pain with severity of at least grade 4 according to VAS). At the end of the first session that was preparation of the access cavity and instrumentation of all canals till master apical file (MAF). The patients were taken one of three drug regimen (single dose) of the study as below: 1-Acetaminophen 325mg, Ibuprofen 200mg with caffeine 40mg [Novafen known named field (the construction company (Brown & burk (uk); 2-Acetaminophen 325mg, Ibuprofen 200mg and 3-Placebo. Then the patients record their severity of pain after 4-6-12-24-48-72 hours after using the drugs, according to the VAS. Meanwhile the patients received a drug pocket that contains 2 tab of Acetaminophen to use if their pain is continuous. In the second session, the canals filled with gutta-percha and ZOE sealer and referred to restore. The data were analyzed with ANOVA test and SPSS software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201306121760N24**

Registration date: **2013-10-27, 1392/08/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-10-27, 1392/08/05

Registrant information

Name

Nargess Gholizadeh Pasha

Name of organization / entity

Fatemehzahra Infertility Reproductive Health
Research Center, Babol University of Medical
Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

zahra@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology, Babol
University of Medical Sciences

Expected recruitment start date

2007-09-23, 1386/07/01

Expected recruitment end date

2008-04-20, 1387/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of analgesic effect - the combination of
acetaminophen and ibuprofen in the presence and
absence of caffeine on pain after root canal treatment

Public title

Comparison of analgesic effect - the combination of acetaminophen and ibuprofen in the presence and absence of caffeine on pain after root canal treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with pain origin molars; patients with spontaneous pain (moderate to severe) based on the criterion of a minimum of four (VAS); patients in the age group 65-18 years old. Exclusion criteria: systemic disease; housing consumption in the last 12 hours; history of allergy to NSAIDs and drugs; pregnant and lactating patients.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **45**

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

The ethics committee of Babol University of Medical sciences

Street address

Babol University of Medical sciences, Ganjafroz Avenue

City

Babol

Postal code

Approval date

2007-08-23, 1386/06/01

Ethics committee reference number

1439

Health conditions studied

1

Description of health condition studied

Pain of acute apical periodontitis

ICD-10 code

K04.4

ICD-10 code description

Acute apical periodontitis of pulpal origin

Primary outcomes

1

Description

Pain after root canal treatment

Timepoint

4, 6, 12, 24, 48 and 72 hours after intervention

Method of measurement

Visual Analog Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Group intervention 1: Acetaminophen 325 mg, Ibuprofen 200 mg and caffeine 40 mg [Novafen known named field (the construction company (Brown & burk (uk); By the Laboratory of Pharmacology, Faculty of Medicine, Babol University of Medical Sciences were divided into three groups of 15. The same drug in capsules (made from gelatin and orange) were placed inside the envelope of a single dose were quite similar and alike.

Category

Treatment - Drugs

2

Description

Group intervention 2: Acetaminophen 325 mg, Ibuprofen 200 mg. By the Laboratory of Pharmacology, Faculty of Medicine, Babol University of Medical Sciences were divided into three groups of 15. The same drug in capsules (made from gelatin and orange) were placed inside the envelope of a single dose were quite similar and alike.

Category

Treatment - Drugs

3

Description

Group Control: placebo. By the Laboratory of Pharmacology, Faculty of Medicine, Babol University of Medical Sciences were divided into three groups of 15. The same drug in capsules (made from gelatin and orange) were placed inside the envelope of a single dose were quite similar and alike.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

The root canal, dental faculty

Full name of responsible person

Mohammad-Kazem Mostafavi

Street address

Vice Chancellor for Research and Technology, Babol
University of Medical Sciences, Ganjafrooz Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology, Babol
University of Medical Sciences

Full name of responsible person

Dr. Ali Bijani

Street address

Vice Chancellor for Research and Technology, Babol
University of Medical Sciences, Ganjafrooz Avenue

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Babol

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research and Technology, 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

Dental College of Babol

Full name of responsible person

Roghayeh Naeimi Tabiei

Position

Dental students

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Dental College of Babol

Full name of responsible person

Dr. Zahra-Sadat Madani

Position

Endodontist

Other areas of specialty/work

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Name of organization / entity

Babol University of Medical Sciences and Research
Centre

Full name of responsible person

Nargess Gholizadeh Pasha

Position

M.A

Other areas of specialty/work

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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