

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Comparison of analgesic effect of Acetaminophen and Acetaminophen Codeine with caffeine in control of control preapical periodontitis pain

Protocol summary

Summary

Pain is among the clinical symptoms of apical acute periodontitis, which could happen spontaneously, moderate to severe, or pain during the contact with the opposite tooth. In order to control the endodontic teeth effectively and based on systematic principles, reaching a diagnosis and then the appropriate treatment such as the drainage of abscess or pulpectomy in case of irreversible inflammation of tooth pulp. Eventually, the suitable medication would be applied in order to decrease the patient's pain. In order to have new components of the medications, to lessen the patient's pains either temporarily or permanently, in this study, the analgesic effect of Acetaminophen and Codeine Acetaminophen in the presence of Caffeine in order to control the pain of acute apical periodontitis were compared. This is a double-blind study. There were 60 patients selected based on the criteria for their inclusion (suffering from severe pain...) and exclusion from the study (suffering from systematic diseases) and divided into 4 groups of 15 subjects. A single dosage was prescribed for each patient: 1. Simple Acetaminophen 325 Mg. + Caffeine 50 Mg. 2. Simple Acetaminophen 325 + Caffeine 100 Mg. 3. Codeine Acetaminophen 15 mg (+ 325 mg) + Caffeine 50 Mg. 4. Codeine Acetaminophen 15 mg (+ 325 mg) + Caffeine 100 mg every 10 mins after the drug consumption according to Visual Analog Scale (VAS) was checked by the patient. During the treatment, the patient was analyzed in terms of the side effects of the medication. At the end, the procedure of the pain was analyzed in different times and a linear graph was drawn for each group. After the investigation and information codes analysis, results in terms of pain reduction was measured in the apical periodontitis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201304121760N22**

Registration date: **2013-08-24, 1392/06/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-08-24, 1392/06/02

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

+98 11 3236 2282

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Recruitment status

Recruitment complete

Funding source

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

Expected recruitment start date

2004-03-17, 1382/12/27

Expected recruitment end date

2005-01-16, 1383/10/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of analgesic effect of Acetaminophen and Acetaminophen Codeine with caffeine in control of control preapical periodontitis pain

Public title

Comparison of analgesic effect of Acetaminophen and Acetaminophen Codeine with caffeine in control of control preapical periodontitis pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Having severe pain scale of 7; Patient's ability to read, write and understand the concept of Visual Analog Scale; Non-housing consumption of 4 hours before the study, aged between 16 and 65 years.
Exclusion criteria: A systemic disease.

Age

From **16 years** old to **65 years** old

Gender

Both

Phase

2-3

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**

Not 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, Gangafroz Avenue

City

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Postal code

4717641367

Approval date

2004-03-15, 1382/12/25

Ethics committee reference number

1153

Health conditions studied**1****Description of health condition studied**

Acute apical periodontitis pain

ICD-10 code

K04.4

ICD-10 code description

Acute apical periodontitis of pulpal origin

Primary outcomes**1****Description**

Acute apical periodontitis pain

Timepoint

Every 10 minutes up to 120 minutes after drug

Method of measurement

Scale Visual Analog Scale (VAS)

Secondary outcomes

empty

Intervention groups**1****Description**

Group Intervention 1. Simple acetaminophen 325mg+caffeine 50mg (Acetaminophen used in the manufacture of pharmaceutical company Galen)

Category

Treatment - Drugs

2**Description**

Group Intervention 2. Simple acetaminophenc 325mg +caffeine 100mg (Acetaminophen used in the manufacture of pharmaceutical company Galen)

Category

Treatment - Drugs

3**Description**

Group Intervention 3. Acetaminophen codeine(325mg +15mg) + Caffeine 50mg (Codeine acetaminophen used in the manufacture of pharmaceutical company Galen)

Category

Treatment - Drugs

4**Description**

Group Intervention 4. Acetaminophen codeine (325mg +15mg) + Caffeine 100mg (Acetaminophen codeine used in the manufacture of pharmaceutical company Galen)

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

The diagnosis and endodontic dental colleges of Babol

Full name of responsible person

Dr. Hosein-Ali Mahran

Street address

Dental Colleges of Babol

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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

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

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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 Colleges Of Babol

Full name of responsible person

Dr. Elham Mahmoodi

Position

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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