Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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
Babol
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
City
Babol

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
Ganjafroz Avenue, Vice Chancellor for Research and Technology, Babol University of Medical Sciences, Gangafroz 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 Colleges Of Babol
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Person responsible for updating data

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Nargess Gholizadeh Pasha
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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