Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Comparison of The prophylactic effect of Zintoma and Ibuprofen in Post-Endodontic pain

Protocol summary

Summary

Pain and discomfort during and after Root canal therapy is the most bothering part of the endodontic treatment. Many drugs have been prescribed to control or eliminate this pain, most of which have undesirable side-effects. Among these; ibuprofen (50-800 mg) has the most decreasing effect on postendodontic pain. Gastro-intestinal problems, are of most important side-effects of NSAIDs . Zintoma a product from Zingiber Officinale has Anti-inflammatory and subsequently analgesic impressions. This study compares the prophylactic effect of Zintoma on postendodontic pain in teeth with irreversible pulpitis, with that of Ibuprofen and placebo. 90 patients who are to be endodontically treated and volunteer to participate in this Double-blind placebo controlled clinical study were randomly assigned into three thirty-person groups. The main inclusion criteria of this study are; irreversible pulpitis of lower first and second molars needing RCT with VAS of 5 or more, ages between 18 and 65 and no history of conflicting disease. The intervention of this study is drug consumption and main outcome measure is pain severity reported by the patient

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903174116N1**
Registration date: **2010-10-10, 1389/07/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-10-10, 1389/07/18

Registrant information

Name

Mohsen Ramazani

Name of organization / entity

Babol university of medical sciences- Faculty of dentistry

Country

Iran (Islamic Republic of)

Phone

+98 32354390111

Email address

m.ramzani@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Babol University of Medical Sciences

Expected recruitment start date

2010-03-20, 1388/12/29

Expected recruitment end date

2011-04-21, 1390/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of The prophylactic effect of Zintoma and Ibuprofen in Post-Endodontic pain

Public title

Comparison of The prophylactic effect of Zintoma and Ibuprofen in Post-Endodontic pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1: Age between 18 and 65 2: No history of the following diseases: mitral valve prolapse, myocardial rheumatism, artificial valve or joint,

myocardial infarction, brain stroke, uncontrolled hypertension, hepatitis, seizure, bleeding disorders, peptic ulcer, liver or kidney diseases 3: No history of allergy to NSAIDs or Zingiber Officinale 4: No pregnancy, no breast feeding 5: No other drug consumption at least four hours before study commense 6: Severity of spontaneous pain must be at least five 7: Patients ability to read, comprehend and complete the questionaire and VAS 8; completion of informed consent

Age
From **19 years** old to **64 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

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
university of medical sciences

Street address
Ganjafrooz avenue

City
Babol

Postal code
4717647745

Approval date
empty

Ethics committee reference number
30.1391.ژ.پ

Health conditions studied

1

Description of health condition studied
Diseases of pulp and periapical tissues

ICD-10 code
K04.0

ICD-10 code description

Primary outcomes

1

Description
pain

Timepoint
before intervention and 4, 8, 12, 24, 48 and 72 hours after intervention

Method of measurement
using VAS registration questionaire

Secondary outcomes

empty

Intervention groups

1

Description
Placebo group: 1.5 hour before treatment, 2 placebo capsules are used and 1 hour later, ie 0.5 hour before treatment another 2 placebo capsules are used

Category
Placebo

2

Description
Ibuprofen group: 0.5 hour before treatment, 1 capsule containing 400 mg ibuprofen is used

Category
Treatment - Drugs

3

Description
Zintoma group: 1.5 hour before treatment two 500 mg zintoma capsules are used and 1 hour later, ie 0.5 hour before treatment another two 500 mg zintoma are used

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Babol University of Medical sciences, Faculty of Dentistry

Full name of responsible person
Dr Mohsen Ramazani

Street address
Ganjafrooz avenue, Medical University, Faculty of Dentistry, Endodontic Department

City
Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Babol University of Medical Sciences

Full name of responsible person
Dr Amrollah Mostafazadeh

Street address
Ganjafrooz avenue-Uneversity of Medical sciences-Faculty of dentistry-Depatment of Endodontics

City
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, 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 Medical University- Faculty of Dentistry

Full name of responsible person
Mohsen Ramazani

Position
Post Graduate Student

Other areas of specialty/work

Street address
Ganjafrooz avenue, Medical University, Faculty of Dentistry, Endodontic Department

City
Babol

Postal code
-

Phone
+98 11 1222 4032

Fax
-

Email
m.ramzani@mubabol.ac.ir

Web page address
-

Person responsible for scientific inquiries

Contact

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Mohsen Ramazani

Position
Post Graduate Student

Other areas of specialty/work

Street address
Ganjafrooz avenue, Medical University, Faculty of Dentistry, Endodontic Department

City
Babol

Postal code
-

Phone
+98 11 1222 4032

Fax
-

Email
m.ramzani@mubabol.ac.ir

Web page address
-

Person responsible for updating data

Contact

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Mohsen Ramazani

Position
Post Graduate Student

Other areas of specialty/work

Street address
Ganjafrooz avenue, Medical University, Faculty of Dentistry, Endodontic Department

City
Babol

Postal code
-

Phone
+98 11 1222 4032

Fax
-

Email
m.ramzani@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