Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Evaluation of the effects of bromelain and acetaminophen in reduce postoperative pain following root canal therapy with symptomatic irreversible pulpitis in comparision with placebo and acetaminophen

Protocol summary

Study aim

Evaluation of the effect of bromelain in reducing pain in patients after endodontic treatment.

Design

A clinical trial with a control group, with parallel groups, two-way blind, randomized, phase 3 on 60 patients and a random number table was used for randomization.

Settings and conduct

The study is performed in special clinics affiliated with the School of Dentistry of the University of Medical Sciences. 60 patients with two mandibular first molars with irreversible pulpitis are selected. After endodontic treatment, half of the patients will be given placebo and acetaminophen every 6 hours and the other half will be given anaheal and acetaminophen capsules every 6 hours until the patients' pain improves.The VAS system is used to measure pain before endodontic treatment and 24, 12, 6 and 48 hours after endodontic treatment.This study is performed in a double-blind manner.Firstly a pharmacist makes anaheal and acetaminophen tablets with a similar apearance and codes one of them as Aa and the other as Ab.Then, an Aa tablet with an acetaminophen pill will be given to half of the patients and an Ab tablet with an acetaminophen will be given to the other half.

Participants/Inclusion and exclusion criteria

Condition of including: age range of all patients is 10 years and above; tooth periapical tssue is normal
Conditions for not including :pregnant women; patients with liver, kidney and coagulation problems or taking anticoagulants

Intervention groups

The intervention group is given acetaminophen and anaheal and the control group is given acetaminophen and placebo. Then, using the VAS system (visual analog scale),Both groups patients' pain is measured before treatment, 24, 12, 6 and 48 hours after it And finally compared.

Main outcome variables

Pain score after endodontic treatment in a questionnaire including VAS (Visual Analog Scale)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210802052051N1**
Registration date: **2021-08-29, 1400/06/07**
Registration timing: **prospective**

Last update: **2021-08-29, 1400/06/07**
Update count: **0**

Registration date

2021-08-29, 1400/06/07

Registrant information

Name

Fatemeh Abbasi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-04, 1400/06/13

Expected recruitment end date

2021-09-26, 1400/07/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of bromelain and acetaminophen in reduce postoperative pain following root canal therapy with symptomatic irreversible pulpitis in comparision with placebo and acetaminophen

Public title

Evaluation of the effect of bromelain on pain after root canal treatment

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The age range of all patients be 10 years and older tooth Periapical tissue be normal

Exclusion criteria:

Pregnant women do not enter the study Patients who have kidney and coagulation problems Patients taking anticoagulants patient has a systemic problem

Age

From **10 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study,a simple randomization method using a table of random number is used.in this study,wich includes 60 samples,the number 00 to 60 are asssigned to the samples.then we randomly select the table point in the row direction.we select numbers smaller than the size of the study population.the select number are the individual code of the community that is selected as the sample.we will continue this until the sample size is complete and reaches the number 60.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is performed in a double-blind manner.Firstly a pharmacist makes anaheal and acetaminophen tablets with a similar apearance and codes one of them as Aa and the other as Ab. Then, an Aa tablet with an acetaminophen pill will be given to half of the patients and an Ab tablet with an acetaminophen will be given to the other half.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics comittee of Isfahan University of Medical Sciences

Street address

IsfahanUniversity Of Medical Science,Hezar jarib Ave

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Isfahan

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Postal code

8174673461

Approval date

2021-06-09, 1400/03/19

Ethics committee reference number

IR.MUI.RESEARCH.REC.1400.106

Health conditions studied

1

Description of health condition studied

Pain after root canal therapy

ICD-10 code

K04.0

ICD-10 code description

Pulpitis

Primary outcomes

1

Description

Pain Score in Visual Analog Scale System (VAS)

Timepoint

Before treatment and 6,12,24and 48hours after treatment

Method of measurement

Visual analog scale

Secondary outcomes

1

Description

Evaluation of the effecacy of bromelaine in reduce postoperative pain following root canal therapy secondary consequences can be a pain reduction score

Timepoint

To measure pain befor root canal therapy , 6 ,12 ,24 and

48 hours after root canal therapy is used .

Method of measurement

Evaluation of the effecacy of bromelaine in reduce postoperative pain following root canal therapy secondary consequences pain reduction score Visual Analogue Scale can be used .

Intervention groups

1

Description

Control group:Half of the samples receiving acetaminophen 500 mg and placebo every 6 hours until the pain improved and their pain before treatment, 24, 12, 6 and 48 hours after treatment were marked on the VAS (Visual Analogue Scale) questionnaire.

Category

Placebo

2

Description

Intervention group:Half of the samples who receive acetaminophen 500mg and Anaheal 500 mg of Promon Amin health brand every 6 hours until the pain improved and their pain before treatment, 24, 12, 6 and 48 hours after treatment were marked on the VAS (Visual Analogue Scale) questionnaire.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental School of Isfahan University of Medical Science

Full name of responsible person

Fatemeh Abbasi

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School of Dentistry, Isfahan University of Medical Sciences, Hezar Jerib St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Fatemeh Abbasi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available