Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Comparison of pre-emptive ibuprofen, acetaminophen, and placebo administration in reducing pain during upper primary molar pulp therapy

Protocol summary

Summary

This study investigates preliminary investigations, whether a pre-emptive analgesia administration reduce pain during pulp therapy. This randomized, double-blind, placebo-controlled trial is planned to compare the efficacy of the pre-emptive administration of ibuprofen, acetaminophen and placebo in reducing pain during pulp therapy in children. Children ages 6–10, presenting at the pediatric clinic of Yazd faculty of dentistry, experiencing spontaneous pain of upper primary molars and with out any systemic diseases or allergic reaction, are considered potential candidates. Seventy-five children are included based on inclusion criteria. The patients are administered a pre-emptive single dose of either: (i) fruit flavored Ibuprofen suspension (100 mg⁄5 mL); 10 mg/kg/dose or (ii) fruit flavored Acetaminophen elixir (120 mg⁄5 mL); 15 mg/kg/dose or (iii) placebo one hour before treatment. Following administration of local anesthesia, pulp therapy is performed. Patients record pain intensity right after the procedure on a five point visual analogue scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014111017935N3**
Registration date: **2015-04-13, 1394/01/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-04-13, 1394/01/24

Registrant information

Name

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Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences of Yazd

Expected recruitment start date

2015-04-01, 1394/01/12

Expected recruitment end date

2015-12-01, 1394/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of pre-emptive ibuprofen, acetaminophen, and placebo administration in reducing pain during upper primary molar pulp therapy

Public title

Use of analgesics in pain reduction in children

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: children ages 6–12, who has primary maxillary molar spontaneous pain; no history of any systemic disease (renal, liver or digestion diseases); no history of prolonged bleeding; no history of platelet disorders; no history of hypersensitivity or allergic reactions to analgesics or any of the drugs tested.
Exclusion criteria: Patients taking analgesics within 5

hours prior to the dental procedure; uncooperative and anxious children.

Age
From **6 years** old to **10 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **75**

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
Ethics Committee of Shahid Sadoughi University of Medical Sciences

Street address
Faculty of Dentistry, Dahe Fajr Blvd, Yazd

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Yazd

Postal code
89195/165

Approval date
2014-07-14, 1393/04/23

Ethics committee reference number
79291

Health conditions studied

1

Description of health condition studied
Pain control during pulptherapy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Pain during pulp therapy

Timepoint
Right after pulp therapy

Method of measurement
Five face Visual Scale

Secondary outcomes

1

Description
Severity of Pain

Timepoint
Right after pulp therapy

Method of measurement
Five face Visual Scale

Intervention groups

1

Description
Fruit flavored Ibuprofen suspension (100 mg/5 mL); 10 mg/kg/dose one hour before treatment.

Category
Treatment - Drugs

2

Description
Fruit flavored Acetaminophen elixir (120 mg/5 mL); 15 mg/kg/dose; one hour before treatment.

Category
Treatment - Drugs

3

Description
Fruit-flavored placebo solution; one hour before treatment.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Dental Faculty of Shahid Sadoughi University of Medical Sciences of Yazd

Full name of responsible person
Narges Amrollahi

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Faculty of Dentistry, Dahe Fajr Blvd, Yazd

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Yazd

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research of Shahid Sadoughi University of Medical Sciences of Yazd
Full name of responsible person
Dr. Fateme Ezoddini Ardakani
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Faculty of Dentistry, Dahe Fajr Blvd, Yazd
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Yazd
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 of Shahid Sadoughi University of Medical Sciences of Yazd
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

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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