Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jul 2026

The effect of premedication With Ibuprofen on intra-operative pain during pulp therapy in primary molars

Protocol summary

Study aim
Evaluation of the effect of premedication with Ibuprofen on the pain during pulp therapy in mandibular primary molars

Design
Double blinded, controlled, randomized clinical trial, with blinded outcome analysis

Settings and conduct
In this study, patient, physician (who recorded the pain score) and statistician was blinded to the groups. A total of 60 patients with 6 to 10 years of old , who visited the clinic of pediatric dentistry in Qazvin Dental School, were randomly divided into two groups. 45 minutes prior to treatment, the child was asked to explain the severity of his/her pain according to the Face Pain Scale-Revised(FPS-R) and placebo or ibuprofen was administered based on the patient's weight (10 mg / kg); then, inferior alveolar nerve block was performed. The access cavity was prepared by dentist and the pain during pulp exposure time was recorded according to FPS-R. Pulp therapy was then accomplished.

Participants/Inclusion and exclusion criteria
inclusion criteria: Children aged 6 to 10 years old; without the history of allergy to the NSAIDs group of drugs; with systemic and mental health and Frankle cooperation level of 3 or 4 ;who had a mandibular primary molar with spontaneous pain that could be restored. Exclusion criteria: Children who had taken any analgesics in previous 24 hours and the teeth requiring other treatments than pulp therapy.

Intervention groups
Intervention group: Ibuprofen Prescribing 120mg/5ml ibuprofen suspension (Emad Darman Pars Co.) according to patient's weight (10 mg/kg), 45 minutes prior to administration of inferior alveolar nerve block. Control group: Placebo(fruit juice) Prescribing placebo according to patient's weight (10 mg/kg), 45 minutes prior to administration of inferior alveolar nerve block.

Main outcome variables
Pain during pulp therapy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200304046693N1**
Registration date: **2020-06-25, 1399/04/05**
Registration timing: **retrospective**

Last update: **2020-06-25, 1399/04/05**
Update count: **0**

Registration date
2020-06-25, 1399/04/05

Registrant information

Name
Hanieh Beikaii

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-04, 1398/01/15

Expected recruitment end date
2020-02-19, 1398/11/30

Actual recruitment start date
2019-04-04, 1398/01/15

Actual recruitment end date
2020-02-19, 1398/11/30

Trial completion date

2020-02-19, 1398/11/30

Scientific title
The effect of premedication With Ibuprofen on intra-operative pain during pulp therapy in primary molars

Public title
Effect of Ibuprofen on the pain during pulp therapy

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Systemic and mental health No history of allergy to the NSAIDs Level of cooperation equal to 3 and 4 in Frankle scale History of spontaneous pain in mandibular primary molar Restorable tooth

Exclusion criteria:
Any contra indication for pulp therapy in clinical and radiographic findings(example:furcation or periapical radiolucensy which involves the permanent tooth bud) Spontaneous pain caused with food impaction Any analgesic consumption in previous 24 hours

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation was done with "Random Allocation Software Version 2.0". This software has been produced to support the first type of randomization. The sample size (60) and number of groups (2 groups) were inserted to the software. The output data was a random sequence of numbers 1 to 60, allocating in two groups of A and B. The sequence was offered to the pharmacist. Bottles including drug (group A) and placebo (group B) was numbered according to the random sequence.

Blinding (investigator's opinion)
Double blinded

Blinding description
A pharmacist prepared placebo and ibuprofen with the same flavor and only the pharmacist was aware of the coded bottles' content. After the completion of treatment, data was sent to the statistician with the codes of 1 and 2. Therefore, patient, physician(who recorded the pain score) and statistician were blinded to the groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee,Qazvin University of Medical Sciences

Street address
Qazvin University of Medical Sciences, Shahid Bahonar Blvd, Qazvin,Iran

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Ghazvin

Province
Qazvin

Postal code
3413786165

Approval date
2019-03-11, 1397/12/20

Ethics committee reference number
IR.QUMS.REC.1397.399

Health conditions studied

1

Description of health condition studied
Primary molars pulpitis

ICD-10 code
K04.0

ICD-10 code description
Pulpitis

Primary outcomes

1

Description
Pain

Timepoint
Before taking drug/placebo, during treatment

Method of measurement
Face Pain Scale- Revised

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Prescribing 120mg/5 ml ibuprofen

suspension(Emad Darman Pars Co.) , 10 mg/kg according to patients weight, 45 minutes prior to treatment.

Category

Prevention

2

Description

Control group: Prescribing placebo(fruit juice), 10 mg/kg according to patients weight, 45 minutes prior to treatment.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Qazvin dental school

Full name of responsible person

Anita Ebrahimi

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Sponsors / Funding sources

1

Sponsor

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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

Qazvin 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

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Full name of responsible person

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Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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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

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

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