Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of ibuprofen premedication on the success of inferior alveolar nerve block anesthesia for primary molars with irreversible pulpitis

Protocol summary

Study aim
The effect of ibuprofen premedication on the success of inferior alveolar nerve block anesthesia for primary molars with irreversible pulpitis

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

Settings and conduct
In this study, patient, physician, the students who introduce pain score sheet to the child and statistician will be blinded to the groups.A total of 42 patients will be randomly divided into two groups. 45 minutes prior to treatment, placebo or ibuprofen will be administered based on the patient's weight (10 mg / kg); then, inferior alveolar nerve block will be performed. 15 minutes after injection, the signs of soft tissue and Lip anesthesia will be examined by a dental explorer. If the patient does not show signs of soft tissue anesthesia,injection will be considered as a failure and the patient will be excluded from the study. The access cavity will then be prepared by dentist and the pain during pulp exposure time will be recorded by the dental assistant. Mild or no pain will be considered as the success of anesthesia and severe or moderate pain will be recorded as a failure.

Participants/Inclusion and exclusion criteria
Inclusion criteria: healthy patients having a carious mandibular primary molar with symptomatic irreversible pulpitis; spontaneous pain of the mentioned tooth; absence of radiolucency in the furcation area. Exclusion criteria: consumption of NSAIDs or other analgesics in the previous 12 hours; allergy to NSAIDs; history of GI disturbances; presence of necrotic pulp tissue after access cavity preparation

Intervention groups
Prescribing placebo or 100mg/5ml ibuprofen suspension according to patient's weight (10 mg/kg), 30 minutes prior to administration of inferior alveolar nerve block

Main outcome variables
Pain during pulp exposure

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20161029030552N3**
Registration date: **2019-03-04, 1397/12/13**
Registration timing: **retrospective**

Last update: **2019-03-04, 1397/12/13**
Update count: **0**

Registration date
2019-03-04, 1397/12/13

Registrant information

Name
yasamin khaksar

Name of organization / entity
shiraz university of medical sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-08-23, 1396/06/01

Expected recruitment end date
2017-10-23, 1396/08/01

Actual recruitment start date
2017-09-23, 1396/07/01

Actual recruitment end date
2017-11-03, 1396/08/12

Trial completion date
2017-11-03, 1396/08/12

Scientific title
The effect of ibuprofen premedication on the success of inferior alveolar nerve block anesthesia for primary molars with irreversible pulpitis

Public title
The effect of ibuprofen on the pain during pulp therapy of mandibular primary molars
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Healthy patients having a carious mandibular primary molar with symptomatic irreversible pulpitis Spontaneous pain of the mentioned tooth Absence of radiolucency in the furcation area
Exclusion criteria:
Consumption of NSAIDs or other analgesics in the previous 12 hours Allergy to NSAIDs History of GI disturbances Presence of necrotic pulp tissue after access cavity preparation
Age
From **6 years** old to **10 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **42**
Actual sample size reached: **42**
Randomization (investigator's opinion)
Randomized
Randomization description
The bottles were numbered by the pharmacist and 42 pockets containing the same number-coded slips of paper, was prepared by a dental aid not associated in the study. In order to allow the patients to be assigned into groups in a random fashion, pockets were introduced to the children and each child received the drug according to the selected pocket.
Blinding (investigator's opinion)
Double blinded
Blinding description
Pharmacist will prepare placebo and ibuprofen with the same flavor and only the pharmacist is aware of the bottles' content. After the completion of treatment, data will be sent to the statistician with the codes of 0 and 1. Therefore, patient, physician, the students who introduce pain score sheet to the child and statistician will be 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 of Shiraz University of Medical Sciences
Street address
Central Building of Shiraz University of Medical Sciences, Karim Khan Zand Ave.
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71348-14336
Approval date
2017-09-23, 1396/07/01
Ethics committee reference number
IR.SUMS.REC.109.1396

Health conditions studied

1

Description of health condition studied
Irreversible pulpitis
ICD-10 code
Pulpitis
ICD-10 code description
K04.0

Primary outcomes

1

Description
Pain
Timepoint
During pulp exposure
Method of measurement
Visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: prescribing Ibuprofen (10 mg/kg) prior to treatment
Category
Prevention

2

Description
Control group: prescribing placebo prior to treatment
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Sahami clinic
Full name of responsible person
Dr. Sara Esmaili
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Sponsors / Funding sources

1

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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
Shiraz 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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Demographic data and the result of statistical analysis of the clinical trial

When the data will become available and for how long
Since the publication of the article

To whom data/document is available
Researchers

Under which criteria data/document could be used
After publication of the article

From where data/document is obtainable
Sending email to the researchers

What processes are involved for a request to access data/document
Sending the request via the email

Comments