

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 71 3725 8091

Email address

khaksar_y@sums.ac.ir

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.

City

Shiraz

Province

Fars

Postal code

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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2nd Abiverdi Ave., Chamran Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz 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

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

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Yasamin Khaksar

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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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