

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the Effects Pre treatment with Acetaminophen and Ibuprofen in Inferior Alveolar Nerve Block of Second Primary Molar Teeth with Irreversible Pulpitis

Protocol summary

Summary

The aim of present study is to compare the effects of pretreatment Acetaminophen and Ibuprofen in inferior Alveolar nerve block in the second primary molar teeth with Irreversible pulpitis. The present study was conducted in a double-blind and randomized manner. The subjects (n=30) were selected in three groups (n=10) from patients referring to the Department of Pediatrics, Tabriz Faculty of Dentistry. Inclusion criteria: children with no history of allergy to Acetaminophen and Ibuprofen; allergy to 2% Lidocaine Anesthetic drugs with 1/200000 epinephrine; no record of intraoral injection; having no unpleasant experience of medical record; phobia from dentistry and no use of analgesic agents during the previous 24 hours periods; mandibular second primary molar with irreversible pulpitis without alveolar abscess. Exclusion criteria: systemic diseases; allergy to lidocaine with 1/200000 epinephrine; allergy to anti-inflammatory nonsteroidal drugs peptic ulcer and use of any pain-killer 24 hours before treatment. Before Local anesthesia, group 1 received 15 mg/kg of Acetaminophen pretreatment in suspension form and group 2 received 5 mg/kg of Ibuprofen pretreatment in syrup form in the same method. Placebo was used in group 3, which was their control group. The patients' pain was measured using visual analogue scale, 5 minutes after injection of the anesthetic agent.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016083129618N2**

Registration date: **2016-09-05, 1395/06/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-09-05, 1395/06/15

Registrant information

Name

Shukufe Najafi Dehkordi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Tabriz University of Medical Sciences

Expected recruitment start date

2016-08-23, 1395/06/02

Expected recruitment end date

2016-08-28, 1395/06/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effects Pre treatment with Acetaminophen and Ibuprofen in Inferior Alveolar Nerve Block of Second Primary Molar Teeth with Irreversible Pulpitis

Public title

Comparison of the Effects Pre treatment with Acetaminophen and Ibuprofen in Success of Anesthesia in the Lower Jaw with Infected Second Primary Molar Teeth

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: children with no history of allergy to Acetaminophen and Ibuprofen; allergy to 2% Lidocaine Anesthetic drugs with 1/200000 epinephrine; no record of intraoral injection; having no unpleasant experience of medical record; phobia from dentistry and no use of analgesic agents during the previous 24 hours periods; mandibular second primary molar with irreversible pulpitis without alveolar abscess. Exclusion criteria: systemic diseases; allergy to lidocaine with 1/200000 epinephrine; allergy to anti-inflammatory nonsteroidal drugs peptic ulcer and use of any pain-killer 24 hours before treatment.

Age

From **6 years** old to **8 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

All drugs were selected from the same pharmaceutical company, packed in similar bottles in the Faculty of Pharmacology of Tabriz and then packed in uniform bottles by a third person, classified in three groups of A, B and C. All the packs were labeled and coded randomly and each patient will receive a pack before injection. The randomized codes were hidden from the researchers, nurses and the patients and will be kept in a safe place until the end of the study (The drug bottles were prepared considering patients weights).

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical

Sciences

Street address

Ethics Committee of Tabriz University of Medical Sciences, Vice Chancellor for Research of Tabriz University of Medical Sciences, Tabriz University of Medical Sciences, Golgasht street, Tabriz

City

Tabriz

Postal code

118-51665

Approval date

2016-08-23, 1395/06/02

Ethics committee reference number

IR.TBZMED.REC.1395.495

Health conditions studied

1

Description of health condition studied

Irreversible pulpitis

ICD-10 code

K04.0

ICD-10 code description

Pulpitis

Primary outcomes

1

Description

Pain Relief after Local Anesthesia Injection

Timepoint

5 minute after Local Anesthesia Injection

Method of measurement

VAS(Visual Analgesic Scale)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1:1 hour Before Local anesthesia, used 15 mg/kg of Acetaminophen pretreatment.

Category

Treatment - Drugs

2

Description

Intervention group 2:1 hour Before Local anesthesia, used 5 mg/kg of Ibuprofen pretreatment

Category

Treatment - Drugs

3

Description

Control group: 1 hour before Local anesthesia used placebo.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Pediatric, Dental Faculty of Tabriz
University of Medical Sciences

Full name of responsible person

Hamed Abadi

Street address

Department of pediatric , Tabriz Dental Faculty,
Tabriz University of Medical Sciences

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Tabriz University of
Medical Sciences

Full name of responsible person

Mohammad Reza Rashidi

Street address

Vice Chancellor for Research, Tabriz University of
Medical Sciences, Golgasht street

City

Tabriz

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, Tabriz University of Medical
Sciences

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

Contact

Name of organization / entity

Department of Pediatric, Dental Faculty of Tabriz

University of Medical Sciences

Full name of responsible person

Hamed Abadi

Position

Assistant Professor

Other areas of specialty/work

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Full name of responsible person

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Position

Assistant Professor

Other areas of specialty/work

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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