

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jul 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

+98 41 3335 5965

###### Email address

shukuh.najafi89@gmail.com

##### 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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**Position**

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**Position**

Assistant Professor

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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*