

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of Effectiveness of Articaine and Lidocaine on Depth of Anaesthesia in Maxillary Primary Molars Teeth

#### Protocol summary

Registration timing: **registered\_while\_recruiting**

#### Study aim

Comparison of effectiveness of articaine and lidocaine on depth of anaesthesia in maxillary primary molars teeth in children 6 to 9 years old

Last update: **2019-12-26, 1398/10/05**

Update count: **0**

#### Registration date

2019-12-26, 1398/10/05

#### Design

Phase III clinical trial with control group and parallel design is double blinded and block randomized. Concealed controlled trial includes 30 patients enrolled between December 2019 and March 2020.

#### Registrant information

##### Name

Nahid Maghsoudi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3781 1631

##### Email address

nahidmaghsoudi@yahoo.com

#### Settings and conduct

The study will be carried out in dentistry faculty, Shahid Sadoughi University of Medical Sciences. Data collector, patients and statistics analyst will not be aware of type of intervention.

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Participants/Inclusion and exclusion criteria

Children 6 to 9 years old who require bilateral extraction of primary maxillary molars and are grade 3 or 4 of frankl behavior rating scale. The tooth is unrestorable and at least one third of the root length has remained. Children have no systemic disease, drug allergy or learning disability, and they have ability of communication in persian language.

#### Expected recruitment start date

2019-12-22, 1398/10/01

#### Expected recruitment end date

2020-03-20, 1399/01/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Intervention groups

The study has two groups. Respectively, articaine in the intervention group and lidocaine in the control group are used as anaesthesia drug in order to extract tooth.

#### Scientific title

Comparison of Effectiveness of Articaine and Lidocaine on Depth of Anaesthesia in Maxillary Primary Molars Teeth

#### Main outcome variables

Pain value using Wong Baker Facial Pain Scale and Face Leg Activity Cry Consolability. Blood pressure and Pulse rate before and after anaesthesia injection and after tooth extraction.

#### Public title

Maxillary Primary Molars Anaesthesia

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191002044953N1**

Registration date: **2019-12-26, 1398/10/05**

##### Purpose

Treatment

## **Inclusion/Exclusion criteria**

### **Inclusion criteria:**

Children who require bilateral extraction of primary maxillary molars Children with grade 3 or 4 of frankl behavior rating scale Unrestorable primary maxillary molars primary maxillary molars with at least one third of the root length Children without systemic disease or drug allergy Children with ability of communication in persian language Children without learning disability

### **Exclusion criteria:**

Uncooperative children Teeth with acute abscess Use of analgesics before treatment Failure in complete anaesthesia after injection

## **Age**

From **6 years** old to **9 years** old

## **Gender**

Both

## **Phase**

3

## **Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

## **Sample size**

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **2**

According to bilateral extraction of the teeth, every patient has two samples.

## **Randomization (investigator's opinion)**

Randomized

## **Randomization description**

Randomization method was blocked. Randomization unit was individual. Randomization tool was sealed envelops. For allocation concealment, two sealed envelops were used for every patient in the first appointment; one determined extraction side and another was for drug type.

## **Blinding (investigator's opinion)**

Double blinded

## **Blinding description**

The principle investigator who is aware of type of intervention would inject and extract tooth. The blinded dentist would collect the data. Considering blinding of data collector and the patient in every appointment, this study is double blinded. Also, the statistics analyst is not aware of type of intervention for each patient.

## **Placebo**

Not used

## **Assignment**

Parallel

## **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

## **1**

### **Ethics committee**

#### **Name of ethics committee**

Ethics Committee of Shahid Sadoughi University of Medical Sciences

#### **Street address**

Dahe Fajr Ave , Imam Reza Square , Dentistry Faculty

#### **City**

Yazd

#### **Province**

Yazd

#### **Postal code**

89148-15669

### **Approval date**

2019-09-17, 1398/06/26

### **Ethics committee reference number**

IR.SSU.REC.1398.104

## **Health conditions studied**

## **1**

### **Description of health condition studied**

Effectiveness of articaine in comparison to lidocaine during maxillary primary molars extraction

### **ICD-10 code**

### **ICD-10 code description**

## **Primary outcomes**

## **1**

### **Description**

Score of self-reported pain by children during maxillary primary molars extraction based on Wong Baker Facial Pain Scale after anaesthesia with lidocaine or articaine

### **Timepoint**

After tooth extraction

### **Method of measurement**

Wong Baker Facial Pain Scale

## **2**

### **Description**

Calculated score of child pain by investigator during maxillary primary molars extraction based on Face Leg Activity Cry Consolability Scale after anaesthesia with lidocaine or articaine

### **Timepoint**

During tooth extraction

### **Method of measurement**

Face Leg Activity Cry Consolability Scale

## **Secondary outcomes**

## **1**

### **Description**

Blood pressure changes before and after tooth extraction

### **Timepoint**

before and after tooth extraction

## Method of measurement

Blood prassure monitor

## 2

### Description

Pulse rate changes before and after tooth extraction

### Timepoint

Before and after tooth extraction

### Method of measurement

Pulse Oximeter

## Intervention groups

## 1

### Description

Intervention group: Injection of 1.8 ml of 4% articaine with 1:100000 epinephrine in buccal infiltration

### Category

Treatment - Drugs

## 2

### Description

Control group: Injection of 1.8 ml of 2% lidocaine with 1:100000 epinephrine in buccal and palatal infiltration

### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Dentistry Faculty of Shahid Sadoughi University of Medical Sciences

#### Full name of responsible person

Nahid Maghsoudi

#### Street address

Dahe Fajr Ave , Imam Reza Square

#### City

Yazd

#### Province

Yazd

#### Postal code

89148-15669

#### Phone

+98 35 3621 4257

#### Email

nahidmaghsoodi@yahoo.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Yazd University of Medical Sciences

#### Full name of responsible person

Masoud Mirzaei

## Street address

No. 2, Shahid Sadoughi Ave., Bahonar Square., Yazd, Iran

## City

Yazd

## Province

Yazd

## Postal code

8916978477

## Phone

+98 35 3724 0171

## Email

masoud\_mirzaei@hotmail.com

## Grant name

## Grant code / Reference number

## Is the source of funding the same sponsor organization/entity?

Yes

## Title of funding source

Yazd 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

Yazd University of Medical Sciences

#### Full name of responsible person

Nahid Maghsoudi

#### Position

Resident of Pediatric Dentistry

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Pediatrics

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## Person responsible for scientific

## **inquiries**

### **Contact**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Nahid Maghsoudi

**Position**

Resident of Pediatric Dentistry

**Latest degree**

Medical doctor

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## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Nahid Maghsoudi

**Position**

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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**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Undetectable information such as age, sex, type of tooth under extraction (first or second molar), amount of root length remaining to be extracted, and previous dental treatments history will be published. Study outcomes will also be published, including changes in blood pressure, pulse rate, Wong-Baker Facial Pain Scale and Face Leg Activity Cry Consolability Scale.

**When the data will become available and for how long**

Starting 9 months after publication.

**To whom data/document is available**

The data are only available for people working in academic institutions.

**Under which criteria data/document could be used**

Use of this data is permitted for systematic review and meta-analysis. Similar clinical trials can also use the data to criticize the present study and its results in their Discussion.

**From where data/document is obtainable**

1. Send an email to nahidmaghsoudi@yahoo.com 2. Send an email to zbahrololoom@yahoo.com 3. Telephone Call with Dr. Zahra Bahrololoomi, No. 983536214257.

**What processes are involved for a request to access data/document**

After the request via one of the three methods listed above, if the request matches the sharing information mentioned before, this information will be available to the applicant within one month.

**Comments**