

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of effectiveness of articaine and lidocaine on depth of anaesthesia in mandibular primary molars teeth

#### Protocol summary

Registration timing: **prospective**

#### Study aim

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

Last update: **2019-12-17, 1398/09/26**

Update count: **0**

#### Registration date

2019-12-17, 1398/09/26

#### 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

Maedeh Rezaei

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 5351 6111

##### Email address

mrezaei2024@gmail.com

#### Settings and conduct

The study was carried out in dentistry faculty, Shahid sadoughi University of Medical Sciences. Data collector , patients and statistice analyst were not aware of type of intervention.

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Participants/Inclusion and exclusion criteria

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

#### Expected recruitment start date

2019-12-21, 1398/09/30

#### Expected recruitment end date

2020-03-19, 1398/12/29

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Intervention groups

The study has two groups, in order to tooth extraction articaine in the intervention group and lidocaine in the control group are used, respectively.

#### Scientific title

Comparison of effectiveness of articaine and lidocaine on depth of anaesthesia in mandibular primary molars teeth

#### Main outcome variables

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

#### Public title

Anesthesia of mandibular primary molars

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191004044977N1**

Registration date: **2019-12-17, 1398/09/26**

##### Purpose

Treatment

## **Inclusion/Exclusion criteria**

### **Inclusion criteria:**

Children aged 6 to 9 years old who require bilateral extraction of primary mandibular molars Children with grade 3 or 4 of frankl behavior rating scale Unrestorable primary mandibular molars Primary mandibular molars with at least on third of the roots Children without systemic disease or drug allergy Children with ability of communication in persian language Children without learning disability

### **Exclusion criteria:**

Ukncooperative children Teeth with acute abcess 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 bilatral extraction of the teeth , every patient has two sampels.

## **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, Denistry Faculty

#### **City**

Yazd

#### **Province**

Yazd

#### **Postal code**

89148-15669

### **Approval date**

2019-09-17, 1398/06/26

### **Ethics committee reference number**

IR.SSU.REC.1398.103

## **Health conditions studied**

## **1**

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

Effectivness of articaeine during mandibular primary molar extraction

### **ICD-10 code**

Y48.3

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

local anaesthesia

## **2**

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

Effectivness of lidocaine during mandibular primary molar extraction

### **ICD-10 code**

Y48.3

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

local anaesthesia

## **Primary outcomes**

## **1**

### **Description**

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

### **Timepoint**

After tooth extraction

### **Method of measurement**

Wong Baker Facial Pain Scale

## **2**

### **Description**

Calculated Score of child pain by investigatore during mandibular primary molars extraction based on Face Leg Activity Cry Consolability Scale after anaesthesia with articaeine or lidocaine

### **Timepoint**

During tooth extraction

## Method of measurement

Face Leg Activity Cry Consolability Scale

mrezaei2024@gmail.com

## Secondary outcomes

### 1

#### Description

Blood pressure changes before and after tooth extraction

#### Timepoint

before and after tooth extraction

#### Method of measurement

Blood pressure 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 epinephrin in buccal infiltration

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Injection of 1/8 ml of 2% lidocaine with 1:100000 epinephrin in buccal infiltration

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dentistry Faculty of Shahid Sadoughi

##### Full name of responsible person

Maedeh Rezaei

##### Street address

Dahe fajr Ave, Immam Reza Square, Shahid Sadoughi University

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Yazd

##### Province

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+98 35 3621 4257

##### Email

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Yazd University of Medical Sciences

##### Full name of responsible person

Masoud Mirzae

##### Street address

Bahonar Square , Central Building of University of Medical Sciences

##### City

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##### Province

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##### Postal code

8916978477

##### Phone

+98 35 3724 0171

##### Email

masoud\_mirzae@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

Maedeh Rezaei

##### Position

Resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Dentistry

##### Street address

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Yazd University of Medical Sciences  
**Full name of responsible person**  
Maedeh Rezaei  
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Resident  
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## Person responsible for updating data

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mrezaei2024@gmail.com

## 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 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 to criticize the present study and its results in their discussion.

### From where data/document is obtainable

Send an email to 1 : mrezaei2024@gmail.com 2: zbahrolloom@yahoo.com

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

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

### Comments