

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

Street address

No. 1, Imam Reza Blvd., Imam Reza Square., Yazd, Iran

City

Yazd

Province

Yazd

Postal code

89148-15669

Phone

+98 35 3621 4257

Email

nahidmaghsoodi@yahoo.com

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

Other areas of specialty/work

Pediatrics

Street address

No. 1, Imam Reza Blvd., Imam Reza Square., Yazd, Iran

City

Yazd

Province

Yazd

Postal code

89148-15669

Phone

+98 35 3621 4257

Email

nahidmaghsoudi@yahoo.com

Person responsible for updating data

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

Street address

No. 1, Imam Reza Blvd., Imam Reza Square., Yazd, Iran

City

Yazd

Province

Yazd

Postal code

89148-15669

Phone

+98 35 3621 4257

Email

nahidmaghsoudi@yahoo.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 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