Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

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

Protocol summary

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

Design
Phase lll 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.

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.

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.

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.

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.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191004044977N1**
Registration date: **2019-12-17, 1398/09/26**
Registration timing: **prospective**

Last update: **2019-12-17, 1398/09/26**
Update count: **0**

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

Registrant information

Name
Maedeh Rezaei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 5351 6111

Email address
mrezaei2024@gmail.com

Recruitment status
Recruitment complete

Funding source

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

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

Public title
Anesthesia of mandibular primary molars

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 whithout 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 articaine or lidocaine

Timepoint

After tooth extraction

Method of measurement

Wong Baker Facial Pain Scale

2

Description

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

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 pressure monitor

2

Description
Pulse rate changes before and after tooth axtraction
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
City
Yazd
Province
Yazd
Postal code
۸۹۱۴۸۱۵۶۶۹
Phone
+98 35 3621 4257
Email
mrezaei2024@gmail.com

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
Yazd
Province
Yazd
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
Dahe fajr Ave, Imam Reza Square, Dentistry Faculty of Shahid Sadoughi university of medical science
City
Yazd
Province

Yazd
Postal code
۸۹۱۴۸-۱۵۶۶۹
Phone
+98 35 3621 4257
Email
mrezaei2024@gmail.com

Person responsible for scientific 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
Dahe Fajr Ave, Imam Reza Sqare, Dentistry Faculty of Shahid Sadoughi university of medical science
City
Yazd
Province
Yazd
Postal code
۸۹۱۴۸-۱۵۶۶۹
Phone
+98 35 3621 4257
Email
mrezaei2024@gmail.com

Person responsible for updating data

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
Dahe fajr Ave, Imam Reza Square, Dentistry Faculty of Shahid Sadoughi university of medical science
City
Yazd
Province
Yazd
Postal code
89148-5669
Phone
+98 35 3621 4257
Email
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 criticiza the present study and its results in their discussion.
From where data/document is obtainable
Send an email to 1 : mrezaei2024@gmail.com 2: zbahrololoom@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