Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Comparison of effectiveness of infiltration of Articaine and block of Lidocaine on pulp therapy of mandibular second primary molar teeth

Protocol summary

Summary

This randomized clinical trial, single-blind, parallel study is done to compare the effectiveness of Lidocaine block and Articaine infiltration in the pulpal treatment of mandibular second primary molar teeth. 40 Children ranging from 6-10 years of age with no history of systemic diseases, allergic reactions and second primary molars without necrosis who were referred to department of pediatrics, College of Dentistry, Yazd, Iran were selected. Children were randomly divided into two groups of Articaine and Lidocaine and after Articaine infiltration or Lidocaine block injection in two separate sessions, vital pulp therapy treatment for second primary mandibular molar was performed. Vital signs and O2 saturation of children were recorded before after injection. Immediately after the treatment session, patient's level of pain was recorded using visual analogue pain scale of five.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015061517935N4**
Registration date: **2016-05-06, 1395/02/17**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-05-06, 1395/02/17

Registrant information

Name
Zahra Bahrololoomi
Name of organization / entity
Shahid Sadoughi University of Medical Sciences-Yazd
Country
Iran (Islamic Republic of)
Phone
+98 35 1624 0691
Email address
zbahrololoom@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences of Yazd

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effectiveness of infiltration of Articaine and block of Lidocaine on pulp therapy of mandibular second primary molar teeth

Public title

Comparison of effectiveness of two anestetic drugs

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:children ages 6–10;healthy children; no history of hypersensitivity to analgesics;children with no learning disability. Exclusion criteria: uncooperative children ;necrosis teeth.

Age

From **6 years** old to **10 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Sadoughi University of Medical Sciences

Street address

Shahid Bahonar Circle,The central building of Shahid Sadoughi University of Medical Sciences, The ethics committee in research, Yazd Iran

City

Yazd

Postal code

Approval date

2015-10-14, 1394/07/22

Ethics committee reference number

IR.SSU.REC.1394.92

Health conditions studied

1

Description of health condition studied

Local anaesthesia

ICD-10 code

Y48.3

ICD-10 code description

Local anaesthetics

Primary outcomes

1

Description

Pain during pulp therapy

Timepoint

Right after pulp therapy

Method of measurement

Five face Visual Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: Before treatment, benzocaine 20% topical anesthetic gel will be applied on dried oral mucosa in injection site area with cotton roll for 1 minute. in test group, infiltration method will be used with 1.8 ml 4% articaine solution with epinephrine 1: 100000 (Septocaine® Septodont Co- France). Injection will be done with a standard aspirating dental syringe and 20 mm, 30 gauge injection needle with injection rate of 1 ml/min. maximum application dose for Articaine is 7 mg/kg.

Category

Treatment - Other

2

Description

Control group: Before treatment, benzocaine 20% topical anesthetic gel will be applied on dried oral mucosa in injection site area with cotton roll for 1 minute. Inferior alveolar nerve block method will be applied with 2% lidocaine solution with 1:100000 epinephrine. Injection will be done with a standard aspirating dental syringe and 20 mm, 30 gauge injection needle with injection rate of 1 ml/min. maximum application dose for lidocaine is 4 mg/kg.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental Faculty of Shahid Sadoughi University of Medical Sciences of Yazd

Full name of responsible person

Donya Alinejhad

Street address

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Sadoughi University of Medical Sciences of Yazd

Full name of responsible person

Fateme Ezoddini Ardakani

Street address

Circle of Bahonar

City

Yazd

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Sadoughi University of Medical Sciences of Yazd

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

Dental Faculty of Shahid Sadoughi University of Medical Sciences of Yazd

Full name of responsible person

Donya Alinejhad

Position

Postgraduate Student of Pediatric Dentistry

Other areas of specialty/work

Street address

Faculty of Dentistry, Dahe Fajr Blvd, Yazd

City

Yazd

Postal code

Phone

+98 35 3726 7525

Fax

Email

donya_alinejhad@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Dental Faculty of Shahid Sadoughi University of Medical Sciences of Yazd

Full name of responsible person

Dr. Zahra bahrololoomi

Position

Associate Professor of Pediatric Dentistry

Other areas of specialty/work

Street address

Faculty of Dentistry, Dahe Fajr Blvd, Yazd

City

Yazd

Postal code

Phone

+98 35 3625 0344

Fax

Email

zbahrololoom@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Dental Faculty of Shahid Sadoughi University of Medical Sciences of Yazd

Full name of responsible person

Donya Alinejhad

Position

Postgraduate Student of Pediatric Dentistry

Other areas of specialty/work

Street address

Faculty of Dentistry, Dahe Fajr Blvd, Yazd

City

Yazd

Postal code

Phone

+98 35 3625 0344

Fax

Email

donya_alinejhad@yahoo.com

Web page address

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