

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Comparison of Effectiveness and Pain Perception of Articain and Lidocain during Dental Second Molar Infiltration in 5-7 Years Old Children

Protocol summary

Summary

Purpose: Comparison of Effectiveness and Pain Perception of Articain and Lidocain due to Dental Second Molar Infiltration in Children Design: Randomized Clinical Trial Population: Children Referred to Pediatric Department of Zahedan Dental School Inclusion Criteria: Healthy 5-7 Years Old Children Who Need Bilateral Buccal Infiltration in Second Primary Molar Exclusion Criteria: Mentally Retarded Children Sample Size: 2 Groups of 20 Subjects Intervention: Evaluating the Effect of Articaine on Efficacy and Pain Perception during Intra Oral Injection Time: During Anesthetic Injection: Reducing the Pain of Intra Oral Injection.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014110213218N3**

Registration date: **2014-11-13, 1393/08/22**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-11-13, 1393/08/22

Registrant information

Name

Elham Hosseini

Name of organization / entity

Zahedan University of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Pardis Chabahar, International Unit

Expected recruitment start date

2014-11-22, 1393/09/01

Expected recruitment end date

2015-01-21, 1393/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Effectiveness and Pain Perception of Articain and Lidocain during Dental Second Molar Infiltration in 5-7 Years Old Children

Public title

Effect of Articaine on the Efficacy and Pain of Intraoral Anesthetic Injection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Healthy 5-7 years old children who need Bilateral Buccal Infiltration Injection in Second Primary Molar and those who will be in cooperative group (Frankle 3-4). Exclusion Criteria: Children with Systemic Disease, Mental Retardation, History of dental treatment, Sensitivity to anesthetics, Taking medications that affect pain.

Age

From **5 years** old to **7 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Zahedan University of Medical Science

Street address
Zahedan University of Medical Science, Dr. Hesabi
Square Zahedan Sistan va Baluchestan Iran

City
zahedan

Postal code
9817699693

Approval date
2014-10-04, 1393/07/12

Ethics committee reference number
6819

Health conditions studied

1

Description of health condition studied
Effectiveness and Pain intensity during Intraoral
Anesthesia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Effectiveness

Timepoint
during treatment

Method of measurement
SEM Scale

Secondary outcomes

1

Description
Pain Intensity

Timepoint
during injection

Method of measurement
SEM Scale

Intervention groups

1

Description
Lidocain 2% with 1/80000 epinephrine, one dose, 1.8 ml
for infiltration anesthesia

Category
Treatment - Drugs

2

Description
Articaine 4%, one dose, with epinephrine 1/100000, for
block or infiltration anesthesia

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Pediatric Department, Zahedan Dental School

Full name of responsible person
Zahra Jami

Street address
Dental School, East Azadegan street

City
Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Pardis Chabahar International Unite

Full name of responsible person
Dr. Hamid Reza Mahmoodzade Sagheb

Street address
Zahedan University of Medical Dr. Hesabi Square

City
Zahedan

Grant name

Grant code / Reference number

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

Title of funding source
Pardis Chabahar International Unite

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

Zahedan University of Medical Science

Full name of responsible person

Zahra Jami

Position

Dental Student

Other areas of specialty/work

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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

Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Elham Hosseini

Position

Assistant Proffesor Specialist in Pediatric Dentistry

Other areas of specialty/work

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