

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the efficacy of Articain 4% and Lidocaine 2% local anesthesia in the maxillary second primary molar in need of pulp therapy.

Protocol summary

Summary

The aim of this study is comparison the efficacy of articaine and lidocaine in controlling pain in the maxillary second primary molar in need of pulp therapy. Patients included in this study were patients with second maxillary molar in need of pulp therapy;no history of infection, abscess and fistula in the tooth;no radiographic sign of intensive internal and external resorption and exclusion criteria were lacking cooperation and teeth with necrotic pulp. The target population is going to be patients attending Pediatric Dentistry Department of Tabriz Faculty of Dentistry at summer and autumn 2014 with maxillary second primary molars in need of pulp therapy, 56 primary maxillary second molar teeth are going to be randomly allocated into two groups. Teeth in group I as a control group will get lidocaine as local anesthesia by posterior superior alveolar nerve block and the second group will get infiltration injection with articaine. After 10 min the caries will be removed and if exposed the clinician will ask patient about the presence or absence of pain.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014122920480N1**

Registration date: **2015-01-23, 1393/11/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-01-23, 1393/11/03

Registrant information

Name

Ensiyeh Maljaei

Name of organization / entity

Faculty of Dentistry, Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3335 5965

Email address

maljaeie@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Tabriz University of Medical Science

Expected recruitment start date

2014-12-18, 1393/09/27

Expected recruitment end date

2015-02-16, 1393/11/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of Articain 4% and Lidocaine 2% local anesthesia in the maxillary second primary molar in need of pulp therapy.

Public title

Comparison of the efficacy of Articain 4% and Lidocaine 2% local anesthesia in the maxillary second primary molar in need of pulp therapy.

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria:patient with second maxillary molar in need of pulp therapy;no history of infection, abscess and fistula in the tooth; children in range of 6-9 (mixed

dentition) years of age; no radio graphic sign of intensive internal and external resorption; consent forms filled by parents; patients with no systemic problems; patients cooperation in 3 or 4 frankle group; crown must be restorable after pulp treatment. exclusion criteria: patients lacking cooperation; teeth with necrotic pulp.

Age

From **6 years** old to **9 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Faculty of Dentistry, Tabriz University of Medical Sciences, Tabriz

City

Tabriz

Postal code

5166614713

Approval date

2014-12-17, 1393/09/26

Ethics committee reference number

93134

Health conditions studied

1

Description of health condition studied

pulpitis

ICD-10 code

K04.0

ICD-10 code description

NOS-acute-chronic (hyperplastic)(ulcerative)-irreversible-reversible

Primary outcomes

1

Description

Pain

Timepoint

10 min after injection

Method of measurement

interview

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patients receive a 1 ml buccal infiltration, 4 percent with 1/100000 epinephrin injection by researcher.

Category

Treatment - Drugs

2

Description

Control group: patients receive a 1 ml block (PSA)anesthesia lidocaine 2 percent with 1/80000 epinephrin injection by researcher.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry,Tabriz University of Medical Science

Full name of responsible person

Ensiyeh Maljaei

Street address

Faculty of Dentistry, Tabriz University of Medical Sciences, Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Tabriz University of Medical Sciences

Full name of responsible person

Dr.Mohammad Reza Rashidi

Street address

Faculty of Dentistry, Tabriz University of Medical Sciences, Tabriz

City

Tabriz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for research of Tabriz University of Medical Sciences

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**

Faculty of Dentistry, Tabriz

Full name of responsible person

Raana Ranjbar Hosseinpour

Position

Student

Other areas of specialty/work**Street address**

Faculty of Dentistry, Tabriz University of Medical Sciences, Tabriz

City

Tabriz

Postal code

5166614713

Phone

+98 41 3335 5956

Fax

+98 41 3334 5977

Email

dr_ranjbar2012@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Faculty of Dentistry, Tabriz University of Medical Science

Full name of responsible person

Dr.Ensiyeh Maljaei

Position

Assistant professor of Pediatric Dentistry

Other areas of specialty/work**Street address**

Faculty of Dentistry, Tabriz University of Medical Sciences, Tabriz

City

Tabriz

Postal code

5166614713

Phone

+98 41 3335 5965

Fax

+98 41 3334 6977

Email

e_maljaei@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Faculty of Dentistry, Tabriz

Full name of responsible person

Dr.Ensiyeh Maljaei

Position

Assistant Professor of Pediatric Dentistry

Other areas of specialty/work**Street address**

Faculty of Dentistry, Tabriz University of Medical Sciences, Tabriz

City

Tabriz

Postal code

5166614713

Phone

+98 914 313 3029

Fax

+98 41 3334 6977

Email

e_maljaei@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*