

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

The effect of tactile or visual determination of injection site on subjective and objective pain reactions and success rate of inferior alveolar nerve block in children

Protocol summary

Summary

One of the most important aspects of behavior management in pediatric dentistry is pain control. The purpose of this study is the effect of tactile or visual determination of injection site on subjective and objective pain reactions and success rate of inferior alveolar nerve block in children. In this double blind randomized clinical trial, 40 children 7-9 years old who need mandibular second primary molars pulpotomy, with no previous dental history and no emergency mode or pulp origin tooth pain, will participate. Slit mouth design will be used in this study, in a way that each child will operate as a self-control and they will be randomly assigned, by the toss of a coin, to receive either tactile or visual mandibular nerve block methods. To make block anesthesia with tactile method is being used of touching coronoid notch for determination of needle insertion site and for visual method, the observation of tip of pterygomandibular triangle is being used. The interval time between two visits will be a week. In second visit, child will received the determination of needle insertion site method that is not used before. Objective pain during injection by the Sound Eyes Motor scale (SEM), subjective pain during injection by Facial Image Scale (FIS) and the success of anesthesia in access cavity preparation by the SEM will be recorded for each two injections. Child and the experimenter of objective pain and success rate of anesthesia will be unaware of determination of needle insertion site method.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT201605116105N5**
Registration date: **2016-06-02, 1395/03/13**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-06-02, 1395/03/13

Registrant information

Name

Nahid Ramazani

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Zahedan University of Medical Sciences

Expected recruitment start date

2016-09-09, 1395/06/19

Expected recruitment end date

2016-10-10, 1395/07/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of tactile or visual determination of injection site on subjective and objective pain reactions and success rate of inferior alveolar nerve block in children

Public title

The effect of tactile or visual determination of injection site on subjective and objective pain reactions and success rate of inferior alveolar nerve block in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: children between 7-9 years old, require treatment in the mandibular second primary molar, a full physical and mental health, located in the classification of Frankel positive or definitely positive during behavioral assessment before treatment, identified the pterygomandibular triangle landmark in intraoral examination. Exclusion criteria: previous dental history, allergies to medication or anesthetic, emergency mode or pulp origin tooth pain, no need to premedication before dental treatment.

Age

From **7 years** old to **9 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)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Crossover

Other design features

-

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Zahedan University of Medical Sciences

Street address

Pardis Department of Zahedan University of Medical Sciences, Khaliqe Fars Boulevard, Dr.Hesabi Square, Zahedan

City

Zahedan

Postal code

9816743463

Approval date

2015-04-19, 1394/01/30

Ethics committee reference number

IR.ZAUMS.rec.1394.32

Health conditions studied**1****Description of health condition studied**

Local anesthesia,

ICD-10 code

Y48.3

ICD-10 code description

Local anaesthetics

Primary outcomes**1****Description**

Objective and subjective pain reaction

Timepoint

During injection and after intervention 1 and 2

Method of measurement

Using SEM scale and using FIS

Secondary outcomes**1****Description**

Success of anesthesia

Timepoint

During access cavity preparation, after intervention 1 and 2 and 5 minutes waiting period

Method of measurement

Using SEM scale

Intervention groups**1****Description**

Intervention 1: Applying topical anesthesia gel (TOPEX, Sultan Healthcare IND. CO, USA) by cotton applicator at the injection site on dried mucosa for 60 seconds, administration mandibular block anesthesia by using visual method to find the needle insertion site by delivering 1 ml of lidocaine %2 with epinephrine 1:80000 (Persocaine-E, Darou Pakhsh IND. CO, Iran) with temperature of 21 °C by using Anthogyr syring (France) with needle gauge 27 and length of 35mm (C- KJECT, CK DENTAL IND. CO, Korea) within 1.5 minutes.

Category

Treatment - Other

2**Description**

Intervention 2: Applying topical anesthesia gel (TOPEX, Sultan Healthcare IND. CO, USA) by cotton applicator at the injection site on dried mucosa for 60 seconds,

administration mandibular block anesthesia by using tactile method to find the needle insertion site by delivering 1 ml of lidocaine %2 with epinephrine 1:80000 (Persocaine-E, Darou Pakhsh IND. CO, Iran) with temperature of 21 °C by using Anthogyr syringe (France) with needle guage of 27 and length of 35mm (C- KJECT, CK DENTAL IND. CO, Korea) within 1.5 minutes.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Pediatric Department, Zahedan dentistry School

Full name of responsible person

Nahid Ramazani

Street address

Zahedan dentistry School, Azadegan East Street,
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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for Research, Zahedan University of
Medical Sciences

Full name of responsible person

Houshang Rafighdoost

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Grant name

7167

Grant code / Reference number

7167

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

Yes

Title of funding source

Vice chancellor for Research, Zahedan 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**

Zahedan dentistry School

Full name of responsible person

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Position

Associate Professor

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Person responsible for updating data**Contact****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