

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison the effect of massage and topical anesthetic gel on the intensity of pain due to inferior alveolar nerve block injection in 5-7 years old children

Protocol summary

Summary

Purpose: Comparison the effect of massage and topical anesthetic gel on the intensity of pain due to inferior alveolar nerve block injection in 5-7 years old children, Design: Randomized Clinical Trial, Population: Children Referred to Pediatric Department of Zahedan Dental School, Inclusion Criteria: Healthy 5-7 Years Old Children Need Bilateral Inferior Alveolar Nerve Block Injection, Exclusion Criteria: Mental Retardation, Children with Systemic Disease, History of dental treatment, History of sensitivity to anesthetics, Taking medications that affect pain, Sample Size: 2 Groups of 30 ones, Subjects Intervention: Comparison the effect of massage on the intensity of pain due to intraoral injection, Pain Time: 5 Minutes Before Using Block Injection, Outcomes: Reducing the Pain of IntraOral Injection.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014111513218N4**
Registration date: **2015-03-20, 1393/12/29**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-03-20, 1393/12/29

Registrant information

Name

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Name of organization / entity

Zahedan University of Medical Science

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Recruitment status

Recruitment complete

Funding source

Zahedan University of Medical Science

Expected recruitment start date

2014-04-04, 1393/01/15

Expected recruitment end date

2014-07-06, 1393/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of massage and topical anesthetic gel on the intensity of pain due to inferior alveolar nerve block injection in 5-7 years old children

Public title

Comparison the effect of massage on the intensity of pain due to anesthetic injection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Healthy children; 5-7 years old; children require Bilateral Inferior Alveolar Injection; Cooperative group (Frankel 3-4). Exclusion Criteria: Children with Systemic Disease; Mental Retardation; History of dental treatment; History of 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: 60

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 addressZahedan University of Medical Science, Dr. Hesabi
Square**City**

Zahedan

Postal code

9816743463

Approval date

2014-06-01, 1393/03/11

Ethics committee reference number

6666

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

Comparison the effect of massage and topical anesthetic gel on the intensity of pain due to inferior alveolar nerve block injection in 5-7 years old children

ICD-10 code

R52.0

ICD-10 code description

pain

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

Pain of Injection

Timepoint

During injection

Method of measurement

Sum of the points of Sound, Eye and Movement according to SEM parameters. point 3(minimum pain intensity) to 12(maximum pain intensity).

Secondary outcomes

empty

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

Intervention 1: In the case group, the injection site will be massaged by finger for 1 minute before injection.

Category

Treatment - Other

2**Description**

Intervention 2: In the control group, topical anesthetic gel "benzocaine" will be applied at the injection site for 1 minute before injection.

Category

Treatment - Other

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

Pediatric Department, Zahedan Dental School

Full name of responsible person

Homa Rastegar

Street address

Dental School, East Azadegan street

City

Zahedan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Zahedan University of Medical Science

Full name of responsible person

Dr. Hooshang Rafighdoost

Street addressZahedan University of Medical Science, 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

Zahedan University of Medical Science

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

Specialist in Pediatric Dentistry

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

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Dental Student

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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

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

Zahedan University of Medical Science

Full name of responsible person

Dr. Elham Hosseini

Position