

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of periodontal ligament injection and inferior alveolar nerve block in mandibular primary molars pulpotomy: A randomized control trial

Protocol summary

Summary

The purpose of this study was to compare the clinical effectiveness of periodontal ligament injection versus block for pulpotomy of mandibular primary molars. The healthy and cooperative children who required pulpotomy entered to this study. 80 children aged 3-7 years old who required pulpotomy in symmetrical mandibular primary molars were selected. These children's teeth were anesthetized with periodontal injection on one side of mandible and block on the other side. Pulpotomy were performed on each patient during the same appointment. Signs of discomfort included hand , body tension and eye movement indicating pain, verbal complaint and crying (SEM scale) , were evaluated blindly by a dental assistant who was not informed about above groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205279882N1**
Registration date: **2012-08-17, 1391/05/27**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-08-17, 1391/05/27

Registrant information

Name

Roza Haghgoo

Name of organization / entity

Shahed University

Country

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Recruitment status

Recruitment complete

Funding source

Research center, Dental School, Shahed University

Expected recruitment start date

2009-09-11, 1388/06/20

Expected recruitment end date

2009-12-11, 1388/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of periodontal ligament injection and inferior alveolar nerve block in mandibular primary molars pulpotomy: A randomized control trial

Public title

Effect of periodontal ligament injection in anesthetizing of in mandibular primary molars

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: children who required pulpotomy on symmetrical mandibular primary molars; were healthy ;did not have any contra indication for local anesthesia; were cooperative. Exclusion Criteria: children were not healthy ; had contra indication for local anesthesia ; were not cooperative.

Age

From **3 years** old to **7 years** old

Gender Both	Signs of discomfort included hand , body tension and eye movement indicating pain, verbal complaint and crying
Phase N/A	Secondary outcomes empty
Groups that have been masked <i>No information</i>	Intervention groups
Sample size Target sample size:	1
Randomization (investigator's opinion) Randomized	Description In experimental group(periodontal ligament injection)0.5ml lidocain Hcl2% was injected in the bottom of the middle part of buccal gingival sulcus
Randomization description	Category Treatment - Drugs
Blinding (investigator's opinion) Triple blinded	2
Blinding description	Description In control group(Block injection) 1.3ml lidocain Hcl2% was injected near inferior alveolar nerve and 0.5 ml was injected in the bottom of sulcus
Placebo Not used	Category Treatment - Drugs
Assignment Parallel	
Other design features	
Secondary Ids empty	
Ethics committees	Recruitment centers
1	1
Ethics committee Name of ethics committee Ethics committee , Shahed University Street address N 72, Italia Str, Vesal Ave City Tehran Postal code Approval date 2009-08-10, 1388/05/19 Ethics committee reference number 2174/1388	Recruitment center Name of recruitment center Dept of Pediatric Dentistry,Dental School, Shahed University Full name of responsible person Vafanoush Street address N71, Italia Str, Vesal Ave City Tehran
Health conditions studied	Sponsors / Funding sources
1	1
Description of health condition studied patient's pain during dental anesthesia ICD-10 code K08.9 ICD-10 code description Disorder of teeth and supporting structures, unspecified	Sponsor Name of organization / entity Research Center, Dental School, Shahed University Full name of responsible person Rezvani Street address N71, Italia Str, Vesal Ave City Tehran Grant name Grant code / Reference number Is the source of funding the same sponsor organization/entity? Yes Title of funding source Research Center, Dental School, Shahed University
Primary outcomes	
1	
Description anesthetizing Timepoint during the treatment Method of measurement	

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

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Tehran

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

Research Center, Dental School, Shahed University

Full name of responsible person

Vafanoush

Position

Masters

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

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Full name of responsible person

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Research Center, Dental School, Shahed University

Full name of responsible person

Rezvani

Position

Assistant Professor

Other areas of specialty/work**Street 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