

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparison of Two Methods: Infiltration anesthesia and inferior Alveolar Block anesthesia in Controlling Pulpotomy's Pain in First Primary Mandibular Molars

Protocol summary

Summary

Introduction: Pain control is an important issue in dentistry. Anaesthetic injection is perhaps the hardest part of treatment in children. The most common method used in mandible area is the inferior alveolar nerve block. As the block injection has a lasting anaesthetic effect in children and could cause traumatic injury to the soft tissue, a substitute injection technique is needed. This study compared two infiltration and block techniques in pain control for pulpotomy in primary first mandibular molars. Materials and methods: In this clinical trial study forty children age between 5 and 8 years were invited to participate. They had the required conditions for the pulpotomy of the mandibular primary first molars. bilaterally. This study used cross over design. The patients were randomly divided into two groups of A and B. The patients in group A received an Infiltration injection in the first right molar and a Block injection on the other side in the first and the second sessions respectively. The patients in group B received a Block injection in first left molar and an Infiltration injection on the other side in the first and the second sessions respectively. The patient's pain was recorded at the instance of injection and the entering the pulp on the based on SEM (Sound Eye Motor) scale. The data was analyzed by "Man whitney U" & "wilcoxon signed rank" tests at 95% confidence level ($P < 0.05$).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201009084714N1**
Registration date: **2010-12-14, 1389/09/23**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-12-14, 1389/09/23

Registrant information

Name

Davoud ghasemi

Name of organization / entity

Islamic Azad University Khorasgan Branch

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2009-02-19, 1387/12/01

Expected recruitment end date

2009-06-05, 1388/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Two Methods: Infiltration anesthesia and inferior Alveolar Block anesthesia in Controlling Pulpotomy's Pain in First Primary Mandibular Molars

Public title

Comparison of Two Methods: Infiltration anesthesia and inferior Alveolar Block anesthesia in Controlling

Pulpotomy's Pain in First Primary Mandibular Molars

Purpose
Treatment

Inclusion/Exclusion criteria
1) age between 5 and 8 2) having the required conditions for the pulpotomy of the mandibular primary first molars bilaterally 3) Not having systemic diseases 4) willing to participate in the study

Age
From **5 years** old to **8 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)
Single blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Islamic Azad University of Khorasgan

Street address
Islamic Azad University of Khorasgan- Dental school - Arghavanieh -Jey St

City
Isfahan

Postal code

Approval date
2007-07-21, 1386/04/30

Ethics committee reference number
638/p

Health conditions studied

1

Description of health condition studied
pulp therapy in primary dentition

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
pain

Timepoint
pulp chamber removal - anesthetic injection

Method of measurement
SEM scale (Sound eye motor)

Secondary outcomes

empty

Intervention groups

1

Description
Infiltration: Injection of anaesthetic solution next to the root of the teeth; pulpotomy: removal of the coronal portion of the pulp in primary teeth

Category
Treatment - Other

2

Description
Mandibular block injection: Injection of anaesthetic solution next to the inferior alveolar nerve- pulpotomy: removal of the coronal portion of the pulp in primary teeth

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Professional Dental Clinics in Isfahan

Full name of responsible person

Street address

City
Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Isalamic Azad university of Khorasgan Branch

Full name of responsible person
Isalamic Azad university of Khorasgan Branch- Dental School

Street address
Isalamic Azad university of Khorasgan Branch- Dental School- Jey St - Arghavnieh

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad university of Khorasgan Branch

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

Islamic Azad University - Dental School

Full name of responsible person

Davood Ghasemi

Position

Assistant Professor of Pediatric Dentistry

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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