Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the mean pain experience during administration of normal and buffered lidocaine by inferior alveolar nerve block in children aged between 7 to 12 years old

Protocol summary

Study aim

1- Determining the average of pain score in patients during local anesthetic injection by regional block technique using normal lidocaine cartridge 2- Determining the average of pain score in patients during local anesthetic injection by regional block technique using buffered lidocaine cartridge 3- Comparing objective 1 and 2

Design

Clinical trials with control group, randomized triple blind, prospective, and crossover

Settings and conduct

The study will be conducted in pediatric dentistry department of Isfahan Dentistry faculty.

Participants/Inclusion and exclusion criteria

Criteria of inclusion for the samples: 1. Samples are selected from 7 to 12 year old patients referring to the specialized department of pediatric dentistry who need similar dental treatment on both sides of the mandible and at least two dental visits. 2. Only patientsare chosen who are classified as level three and four (positive and completely positive) of Frankl's behavioral classification. 3. Patients should not have any systemic problems, mental and physical disabilities, or any history of allergies to lidocaine and sulfite. Exclusion criteria for the samples: 1. Patients whose parents are reluctant to participate in the study are excluded. 2. Teeth that have a local or diffused infection (abscess or cellulitis). 3. Patients who are agitated because of severe dental pain. 4. Children who have any oral lesions (such as aphthous ulcer, mucositis, etc.) in the anesthetic injection site.

Intervention groups

In intervention group 1 ml of Lidocaine 2% solution in combination with 0.2 ml solution of sodium bicarbonate 8.4% solution will be used and in control group lidocaine 2% solution will be used for mandibular local anesthetic with block technique respectively.

Main outcome variables

Pain during injection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170722035235N2**
Registration date: **2018-07-28, 1397/05/06**
Registration timing: **prospective**

Last update: **2018-07-28, 1397/05/06**
Update count: **0**

Registration date

2018-07-28, 1397/05/06

Registrant information

Name

Alireza Eshghi

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2018-10-23, 1397/08/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the mean pain experience during administration of normal and buffered lidocaine by inferior alveolar nerve block in children aged between 7 to 12 years old

Public title
Comparison of the mean pain experience during administration of normal and buffered lidocaine
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Only patients are chosen who are classified as level three and four (positive and completely positive) of Frankl's behavioral classification. Patients are selected when their parents are willing to participate in the study after being informed by the consent form. Patients should not have any systemic problems, mental and physical disabilities, or any history of allergies to lidocaine and sulfite.
Exclusion criteria:
Patients whose parents are reluctant to participate in the study are excluded. Teeth that have a local or diffused infection (abscess or cellulitis). Patients who are agitated because of severe dental pain.
Age
From **7 years** old to **14 years** old
Gender
Both

Phase
4
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
The distribution of the patients in the control and intervention groups is performed using a randomized simple sampling method using random numbers table.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The individual giving the local anesthetic injection, the patient, and the Statistics expert do not know which group of intervention or control the patient is.
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Department of Pediatric Dentistry, School of Dentistry, Hezar Jerib St, Isfahan University of Medical Sciences
City
Isfahan
Province
Isfehan
Postal code
8174884841
Approval date
2018-07-11, 1397/04/20
Ethics committee reference number
IR.MUI.REC.1397.300199

Health conditions studied

1

Description of health condition studied
Comparison of the mean pain experience during administration of local anesthesia
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pain score using Visual Analog Scale
Timepoint
Measuring the pain score during injection
Method of measurement
Using the Visual Analog Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:
Category
Treatment - Drugs

2

Description
Control group:
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan University of Medical Sciences
Full name of responsible person
Hamid Mosleh
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Department of Pediatric Dentistry, School of Dentistry, Hezar Jerib St, Isfahan University of Medical Sciences
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr Omid Savabi
Street address
بخش دندانپزشکی کودکان،دانشکده دندانپزشکی اصفهان، دانشگاه علوم پزشکی اصفهان، خیابان هزار جریب
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr Mehdi Jafarzadeh
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Resident
Latest degree
Medical doctor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable