

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 patients are 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)

Phone

+98 31 3792 5591

Email address

eshghi@dnt.mui.ac.ir

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

Isfahan

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

Street address

Department of Pediatric Dentistry, School of Dentistry, Hezar Jerib St, Isfahan University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code

8174884841

Phone

+98 31 3777 2822

Email

mosleh_hamid@yahoo.com

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

City

Isfahan

Province

Isfahan

Postal code

8174884841

Phone

+98 31 3777 2822

Email

mosleh_hamid@yahoo.com

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

Dentistry

Street address

Department of Pediatric Dentistry, School of Dentistry, Hezar Jerib St, Isfahan University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code

8174884841

Phone

+98 31 3777 2822

Email

mejsamani@yahoo.co.uk

Person responsible for scientific 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

Dentistry

Street address

Department of Pediatric Dentistry, School of Dentistry, Hezar Jerib St, Isfahan University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code

8174884841

Phone
+98 31 3777 2822
Email
mejsamani@yahoo.co.uk

8174884841
Phone
+98 31 3777 2822
Email
mosleh_hamid@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Hamid Mosleh
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
Street address
Department of Pediatric Dentistry, School of
Dentistry, Hezar Jerib St, Isfahan University of Medical
Sciences
City
Isfahan
Province
Isfahan
Postal code

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