Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Aug 2026

Comparison of the Effect of Needle Gauge on Pain and Anxiety of Children During Palatal Infiltration Anesthesia

Protocol summary

Study aim
The purpose of this study is comparison of the effect of needle gauge on pain and anxiety of 4_8 years old children during palatal infiltration anesthesia

Design
Clinical trial with two groups of intervention, without control group, with cross over groups, double blind, randomized

Settings and conduct
This study will be conducted at the private clinic of Hamid Sarlak, a pediatric dentistry specialist in the city of Arak. For each patient, according to the groups assigned in one session, the palatal anesthesia will be injected with 27 or 30 gauge in one side and at the next session with another gauge on the opposite side. The level of anxiety and pain will be measured by the heart rate, sound eye motor (SEM), and face pain rating(FPR) at treatment sessions. The present study is a double-blind study because the patient and dentist assistant(questionnaire information recorder) are unaware of how individuals are assigned to groups.

Participants/Inclusion and exclusion criteria
60 children 4 to 8 years old at children's dentistry office in Arak city in year 99_98 inclusion criteria:children 4 to 8 years old candidate for double sided pulpotomy and stainless steel crown (SSC) in the first or second primary maxillary molars of the same type They are healthy genetically, systemic and learning ability They have no history of dental treatment and hospitalization In Frankel cooperation scale should be in positive or definitely positive position Exclusion criteria:existence of severe pain or obvious need for treatment on a side earlier of opposite side that excludes the study from random state.

Intervention groups
Group 1: First session Needle gauge 30 Second session Needle gauge 27 Group 2: First session Needle gauge 27 Second session Needle gauge 30

Main outcome variables
Pain; Anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190702044078N1**
Registration date: **2020-05-23, 1399/03/03**
Registration timing: **retrospective**

Last update: **2020-05-23, 1399/03/03**
Update count: **0**

Registration date
2020-05-23, 1399/03/03

Registrant information

Name
Zohre Salimi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 26 3272 1601

Email address
zohre.salizs@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-11-22, 1398/09/01

Expected recruitment end date
2019-12-22, 1398/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of the Effect of Needle Gauge on Pain and Anxiety of Children During Palatal Infiltration Anesthesia

Public title
Effect of Needle Gauge on Pain and Anxiety During Dental Anesthesia
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
All patients should be candidates for double-sided pulpotomy and stainless steel crown (SSC) in the first or second primary maxillary molars of the same type They are genetically, systemic and able to learn healthy They have no history of dental treatment and hospitalization In Frankel cooperation scale should be in positive or definitely positive position
Exclusion criteria:
Existence of severe pain or obvious need for treatment on a side earlier of opposite side that excludes the study from a random state
Age
From **4 years** old to **8 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**
More than 1 sample in each individual
Number of samples in each individual: **2**
Child with first or second primary molars similarly on both sides of the maxilla, that require pulpotomy and stainless steel crown.
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method: Simple Randomization Unit: Individual Randomization tool: To place the subjects in two groups based on the needle gauge priority in the injection of anesthesia using SPSS software version 16 and to select the maxillary quadrant in the third session of 60 completely identical envelopes with half of them zero And in half number one is used. During the first treatment session, the envelope will be moved, then a envelope will be selected for each child. If the number is zero the treatment is on the right and if the number is one the treatment is on the left. Hiding is done by uniform and black envelopes.
Blinding (investigator's opinion)
Double blinded
Blinding description
The present study is a double-blind study because the patient and the dentist assistant (questionnaire information recorder) are unaware of how individuals are assigned to groups and the type of intervention performed at each session to treat individuals(use 27 or 30 gauge needle).
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak university of medical sciences
Street address
Academic complex of the Great prophet, Basij squre, Sardasht
City
Arak
Province
Markazi
Postal code
3819693345
Approval date
2019-08-04, 1398/05/13
Ethics committee reference number
IR.ARAKMU.REC.1398.135

Health conditions studied

1

Description of health condition studied
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pulse rate
Timepoint
Heart rate at each treatment session (third and fourth sessions) is measured three times and recorded by the dentist's assistant: 1. After sitting the child on the unit (one minute before injection) 2. 10 seconds after local anesthetic injection 3. During the pulp exposure.
Method of measurement
To test the heart rate, the digital electronical device OXY300 (Microlife AG, Widnau, Switzerland) will be used by placing the probe on the child's left hand finger.

2

Description
Face pain rating
Timepoint

After injection of anesthesia

Method of measurement

The subjective evaluation of pain is performed by the FPR scale after the injection of an anesthesia drug, which is recorded by the child using its scoring image, and determined score by the next session in the presence of another gauge are compared.

3

Description

evaluation of pain by eye, movement and sound (SEM)

Timepoint

During injection of anesthesia

Method of measurement

The Objective scale used to measure pain is the SEM scale that evaluates the sound, eyes, and movements of the child according to the score table. The score is measured and recorded by the dentist's assistant during injection of anesthesia with a needle gauge and at the next meeting with another gauge and will be compared.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Anesthesia injection of palatal infiltration with gauge 30 needle. Anesthetizing agent used for all patients is Lidocaine 2% E_80, Daroupakhsh, that with C-Kject needle by conventional infiltration of palatal with ICT injection device of the Genoss company at 0.2 ml will be injected.

Category

Prevention

2

Description

Intervention group: Intervention group: Anesthesia injection of palatal infiltration with gauge 27 needle. Anesthetizing agent used for all patients is Lidocaine 2% E_80, Daroupakhsh, that with C-Kject needle by conventional infiltration of palatal with ICT injection device of the Genoss company at 0.2 ml will be injected.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr Hamid Sarlak's office Pediatric Dentistry

Full name of responsible person

Hamid Sarlak

Street address

Fifth Floor, Mir Ahmad Building, Azod Corner, Shahid Beheshti Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr.Mohammad Arjmandzadegan

Street address

Academic Complex of the Great Prophet, Basij Square, Sardasht

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Hamid Sarlak

Position

Associate professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Person responsible for scientific inquiries

Contact

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Position
Student

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A Level or less

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
All data are publishable.

When the data will become available and for how long
One year after publishing results

To whom data/document is available
All researcher in university and research centers

Under which criteria data/document could be used
There are no conditions

From where data/document is obtainable
Dr Hamid Sarlak

What processes are involved for a request to access data/document
Request a person by email Investigating university affiliation of the requesting person send information via email the maximum time of this process is one month

Comments