

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jun 2026

The Comparison of the Effect of Needle Gauge on Pain and Anxiety of Children During Articaine Mandibular Buccal Infiltration Anesthesia

Protocol summary

The outcome of all studies is to measure pain and anxiety.

Study aim

The aim of this study was to compare the amount of pain in injecting articular infiltration anesthesia in the mandibular buccal area in children aged 4 to 8 years using needles with confusion 27 and 30.

Design

Clinical trial with control group, with parallel groups, three-way blind, randomized, phase 2 on 60 patients. To randomize in this study, SPSS software version 16 is used to place children in groups 1 or 2 based on the priority and delay of needle confusion in anesthesia injection. Also, 60 very similar envelopes were used in the third session to select the lower jaw quadrant, half of which is zero and the other half is one.

Settings and conduct

This study is a clinical trial (Split Mouth) and will be performed as a split on clients in the private office of a pediatric dentist. In this study, the samples are divided into two main groups. In the first group, first in the first session of treatment. First, a one-way (left or right) mandibular injection needle with 30 gauge needle will be used.

Participants/Inclusion and exclusion criteria

1. All specialists must have a candidate for the required functions who use bilateral pulpotomy and SCC in Miller Dentistry. 2. Genetically, systematically and observing a healthy learner. 3. Due to the fact that we can have a distribution limit using a specialist doctor. 4. You can be positive (positive) or completely positive (definitely definitely positive) in terms of Frankl's cooperation criteria.

Intervention groups

For those who participated in this study, based on what was said in the implementation section, Bacal anesthesia injection was one of the 27 and 30 gauge needles in the first session of treatment on one side of the mandible and the needle with another gauge in the second session of treatment on the opposite side of the jaw will be done.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200509047369N1**

Registration date: **2020-05-21, 1399/03/01**

Registration timing: **prospective**

Last update: **2020-05-21, 1399/03/01**

Update count: **0**

Registration date

2020-05-21, 1399/03/01

Registrant information

Name

Mohammad Najafi haghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3774 3096

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of the Effect of Needle Gauge on Pain and Anxiety of Children During Articaine Mandibular Buccal Infiltration Anesthesia

Public title

The Comparison of the Effect of Needle Gauge on Pain and Anxiety of Children During Articaine Mandibular Buccal Infiltration Anesthesia

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients should be candidates for similar treatment for bilateral pulpotomy and SCC in the first molar teeth of the mandible They are genetically, systemically and capable of healthy learning They also have no history of dentistry and hospitalization. In terms of cooperation criteria, Frankel is in a positive or 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
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Teaching method: simple Decision Making Unit:
Possibility Tools for providing services: To have a license in two groups based on demand and Thatcher Gage needle in the field of anesthesia injection using lottery and to select quadrant jaw in providing 60-person services, you can control half of the number once by using your normal resources. . Created by single and black envelopes 1: First consultation session: Gage needle 30 Second session: Gage needle 27 Group 2: First consultation session: Gage needle 27 Second session: Gage needle 30

Blinding (investigator's opinion)

Triple blinded

Blinding description

The present study is of the three Socor type, as the patient, dentist, and statistical analyzer are unaware of how individuals are assigned to groups and the type of intervention performed at each session to treat

individuals.

Placebo

Not used

Assignment

Parallel

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 Payambar Azam, Basij square, Sardasht

City

Arak

Province

Markazi

Postal code

3819693345

Approval date

2020-05-06, 1399/02/17

Ethics committee reference number

IR.ARAKMU.REC.1399.025

Health conditions studied**1****Description of health condition studied**

The Comparison of the Effect of Needle Gauge on Pain and Anxiety of Children During Articaine Mandibular Buccal Infiltration Anesthesia

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes**1****Description**

Pulse rate

Timepoint

The heart rate is measured three times in each treatment session (third and fourth sessions) and recorded by the dentist's assistant. 1. After the child sits on the unit (one minute before the injection) 2. 10 seconds after the start of the anesthesia injection Topical 3. At the time of pulp exposure.

Method of measurement

The OXY300 digital electronic device (microlife AG.widnau.swit Switzerland) will be used to check the

heart rate by placing the probe on the index finger of the child's left hand.

2

Description

face pain rating

Timepoint

after injection of anesthesia

Method of measurement

Subjective measurement of pain is performed by FPR criteria after injection of anesthetic, which is recorded by the child using its scoring image and the score is compared with the next session in the presence of another confusion.

3

Description

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

Timepoint

during injection of anesthesia

Method of measurement

The objective criterion used to assess the amount of pain is the SEM criterion, which assesses the condition of the child's eyes and movements according to the scoring table. The score is determined by the dental assistant during the injection of anesthesia with one of the needle beads in the session. They will then be measured and recorded with Digger's gauge and compared.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: injection of buccal maxillary infiltration anesthesia containing gauge needle 30. Anesthesia material is possible for you so that you can use articine as a c-kject needle by focal buccal infiltration with special features of ICT injection of genoss partners to 0.2 services. Intense collision

Category

Prevention

2

Description

Intervention group: injection of buccal maxillary infiltration anesthesia containing gauge needle 27. Anesthesia material is possible for you so that you can use articine as a c-kject needle by focal buccal infiltration with special features of ICT injection of genoss partners to 0.2 services. Intense collision

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Office of Doctor Hamid Sarlak

Full name of responsible person

Hamid Sarlak

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

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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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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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available