Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of dentistry anesthetic temperature on pain perception during inferior alveolar nerve block injection

Protocol summary

Study aim

Determination of the effect of dentistry anesthetic temperature on pain perception during inferior alveolar nerve block injection

Design

The present study is a parallel double-blind, randomized clinical trial on 23 patients. Excel software rand function will be used for randomization.

Settings and conduct

The present study was performed on volunteer medical students of Kurdistan University of Medical Science who have inclusion criteria and no exclusion criteria, in the period between September and October 1400 after obtaining informed and written consent in the pediatric ward of Kurdistan Dental School.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Medical students aged 18 to 25 years in the ASA I physical classification in terms of physical condition classification. Exclusion criteria: any pain, swelling, abscess or infection at the injection site, Allergic to lidocaine, systemic diseases, and contraindications to epinephrine in individuals, the presence of neuropathy in the face, and the use of NSAIDs, various analgesics, benzodiazepines, and anti-Depression in the two weeks before the intervention.

Intervention groups

Case group: The inferior alveolar nerve block is injected into one side of the mandible with DarouPakhsh Company Carpule of 2% lidocaine containing epinephrine 1: 80,000 is administered. Control group: After one week, On the opposite side of the mandible, the inferior alveolar inferior nerve block is injected with carpule containing an anesthetic solution at a temperature of 37 degrees (body temperature).

Main outcome variables

Pain perception

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210714051890N1**
Registration date: **2021-09-01, 1400/06/10**
Registration timing: **prospective**

Last update: **2021-09-01, 1400/06/10**
Update count: **0**

Registration date

2021-09-01, 1400/06/10

Registrant information

Name
Parisa Heydari

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 87 3362 8096

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heydariparisssa@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-11, 1400/06/20

Expected recruitment end date

2021-10-02, 1400/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of dentistry anesthetic temperature on pain perception during inferior alveolar nerve block injection

Public title
Evaluation of the effect of anesthetic temperature on pain perception in dental injections
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Volunteer medical students 18 to 25 years old Healthy patients meeting the criteria of ASA physical status 'I'
Exclusion criteria:
Any pain, swelling, abscess or infection at the injection site Allergic to lidocaine Presence of systemic diseases and contraindication to epinephrine in individuals Presence of facial neuropathy Taking NSAIDs, painkillers, benzodiazepines and antidepressants in the two weeks before the intervention
Age
From **18 years** old to **25 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **23**
More than 1 sample in each individual
Number of samples in each individual: **2**
Both sides of the jaw will be used as an example.
Randomization (investigator's opinion)
Randomized
Randomization description
The first injection in the mandible of half of the subjects was performed with anesthetic solution at a temperature of 37 degrees and in half of the subjects with a solution of 21 degrees. The subjects are numbered and randomly using Excel randomization method, we determine in which people the first injection should be done with anesthetic solution at 37 degrees and in which people with anesthetic solution at 21 degrees. And then we randomly determine with the same method that the first injection is done on the left side of the lower mandible or the right side.
Blinding (investigator's opinion)
Double blinded
Blinding description
The injector and the person being injected will not know the temperature of the anesthetic solution and the pain will be assessed by the injector who is unaware of the temperature of the anesthetic carpule.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kurdistan University of Medical Sciences
Street address
Kurdistan University of Medical Sciences, Pasdaran Blvd
City
Sanandaj
Province
Kurdistan
Postal code
6617713446
Approval date
2021-08-31, 1400/06/09
Ethics committee reference number
IR.MUK.REC.1400.127

Health conditions studied

1

Description of health condition studied
pain
ICD-10 code
G89.18
ICD-10 code description
Other acute postprocedural pain

Primary outcomes

1

Description
Pain score
Timepoint
Immediately after the first and second injections
Method of measurement
pain Visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Inferior alveolar nerve block dentistry injection by direct method, with a 27-gauge needle and 1.8 ml of DarouPakhsh Company Carpule of 2% lidocaine

containing epinephrine 1: 80,000 is administeredat with 21 °C (room temperature), to one side of the mandible of the participant in the study.The injection is performed by a dental specialist.

Category

Prevention

2

Description

Control group: Inferior alveolar nerve block dentistry injection by direct method , with a 27-gauge needle and 1.8 ml of DarouPakhsh Company Carpule of 2% lidocaine containing epinephrine 1: 80,000 is administered , which is brought to a temperature of 37 °C (body temperature) using a heater. Towards the opposite side of the mandible of the person participating in the study.The injection is performed by a dental specialist.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Kurdistan University of Medical Sciences, Faculty of Medicine

Full name of responsible person

Soma Arabzade Moghadam

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Faculty of Dentistry, Kurdistan University of Dentirtry, Pasdaran Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Afshin Maleki

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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

Sanandaj 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

Sanandaj University of Medical Sciences

Full name of responsible person

Parisa Heydari

Position

Dentistry intern

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Full name of responsible person

Soma Arabzade Moghadam

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is from the proposal, raw data and project reports

When the data will become available and for how long

Data is available from the legal system six months after publication for two years

To whom data/document is available

All persons will be able to access the Kurdistan University of Medical Sciences's request to the Kurdistan University of Medical Sciences

Under which criteria data/document could be used

For legal issues and the need to use data in future studies

From where data/document is obtainable

Soma Arabzade Moghadam, Parisa Heydari

What processes are involved for a request to access data/document

After submitting a request to the research and technology secretary of Kurdistan University of Medical Sciences, the call should be held to the administrator for supply.

Comments