Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The Effect of Diaphragmatic Breathing on Reducing Anxiety During Inferior Alveolar Nerve Block in Children Aged 6 to 12

Protocol summary

Study aim
Determining the effect of diaphragmatic breathing in reducing anxiety during inferior alveolar nerve block in children aged 6 to 12 years

Design
Randomized clinical trial with parallel groups and control, no blinding, using block randomization via sealed envelopes, on 60 children.

Settings and conduct
School of Dentistry, Semnan University of Medical Sciences To determine the patient's anxiety level, we monitor the child's blood oxygen saturation before and after the injection with a pulse oximeter. We also use the child's pulse count to check the fluctuations in the child's heart rate before and after the injection of anesthesia.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Age: Children between 6 and 12 years old. Need for inferior alveolar nerve block: Children requiring inferior alveolar nerve block for dental procedures. Anxiety level: Children with normal anxiety levels based on initial assessments and who meet the required score on the questionnaire. Exclusion Criteria: Medical conditions: Children with medical issues that may affect the impact of diaphragmatic breathing (e.g., acute respiratory problems). Anti-anxiety medications: Children currently taking anti-anxiety drugs that may influence their anxiety levels. Unwillingness to continue: Children or parents who are unwilling to continue participation or unable to attend sessions regularly.

Intervention groups
Intervention group: Children who were taught diaphragmatic breathing techniques before the inferior alveolar nerve block injection and then asked to do this breathing during the injection. Control group: Children who received the inferior alveolar nerve block using only the Tell-Show-Do technique, without teaching or practicing diaphragmatic breathing.

Main outcome variables
Diaphragmatic breathing; Anxiety; Blood oxygen saturation; Heart rate; Age; Gender

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250126064530N1**
Registration date: **2025-06-07, 1404/03/17**
Registration timing: **prospective**

Last update: **2025-06-07, 1404/03/17**
Update count: **0**

Registration date
2025-06-07, 1404/03/17

Registrant information

Name
Ali Shojaeian

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 23 3345 4088

Email address
ali.shojae777@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-06-15, 1404/03/25

Expected recruitment end date
2025-11-16, 1404/08/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The Effect of Diaphragmatic Breathing on Reducing Anxiety During Inferior Alveolar Nerve Block in Children Aged 6 to 12

Public title
The Effect of Diaphragmatic Breathing on Reducing Anxiety During Inferior Alveolar Nerve Block in Children Aged 6 to 12

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Children in need of inferior alveolar nerve block

Exclusion criteria:
Medical problems: Children who have medical problems that may affect diaphragmatic breathing (such as acute breathing problems). Anti-anxiety medications: Children who are currently taking anti-anxiety medications that may affect their anxiety levels. Reluctance to continue: Children or parents who are unwilling to continue to participate in the study or who cannot attend meetings regularly. Failure to follow instructions: Children who are unable to follow the instructions for practicing diaphragm breathing or who have not followed the instructions during the study period.

Age
From **6 years** old to **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Blocked Randomization Sampling Method The blocked randomization sampling method is used to allocate patients to intervention and control groups in a random and organized manner. This method is described as follows: Each treatment method is assigned a code. Codes are written according to the number of intervention and control groups. The codes are placed inside sealed envelopes. The children entering the study are divided into blocks of four. Each patient in a block randomly selects one of the envelopes. The code inside the envelope determines to which intervention or control group the patient is assigned.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features
After the project is approved by the university's research ethics committee and the clinical trial registration is completed by visiting the Semnan Dental School's special clinic and obtaining a permit, children aged 6 to 12 who are eligible for inclusion will enter the study. We will divide the 6 to 12-year-old patients who need our inferior alveolar nerve block and who have visited the Semnan Dental School and have been included in the study with the inclusion criteria into two equal groups. For one group (control group), we will inject the inferior alveolar nerve block using the tell-show-do technique, and for the other group (experimental group), we will teach diaphragmatic breathing before injecting the inferior alveolar block anesthetic, and then ask the patient to do diaphragmatic breathing in this way before the injection.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Semnan University of Medical Sciences

Street address
Headquarters of Semnan University of Medical Sciences and Health Services, Basij Boulevard, Semnan, Semnan Province

City
Semnan

Province
Semnan

Postal code
3514799442

Approval date
2024-12-09, 1403/09/19

Ethics committee reference number
IR.SEMUMS.REC.1403.228

Health conditions studied

1

Description of health condition studied
Children's anxiety

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Anxiety levels in children during inferior alveolar nerve block

Timepoint
Before and during the intervention

Method of measurement

Spence Children's Anxiety Scale - SCAS

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Children who were taught the diaphragmatic breathing technique before the inferior alveolar nerve block injection and then asked to perform this breathing during the injection.
Category
Other

2

Description
Control group: Children who received inferior alveolar nerve block using only the Tell-Show-Do technique, without training or practicing diaphragmatic breathing.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Semnan Dental School
Full name of responsible person
Mona Nasiri
Street address
Semnan Dental School, 17 Shahrivar Boulevard, Semnan
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3518794431
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Dr. Ali Rashidipour
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Headquarters of Semnan University of Medical Sciences and Health Services, Basij Boulevard, Semnan, Semnan Province
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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
Semnan 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
Semnan University of Medical Sciences
Full name of responsible person
Mona Nasiri
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Pediatrics
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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

The dataset includes anonymized clinical and demographic data of dental patients involved in the study, including treatment outcomes, radiographic images, and questionnaire responses related to oral health status and treatment satisfaction. Only de-identified participant-level data relevant to primary and secondary endpoints will be shared.

When the data will become available and for how long

Access to the data will begin 3 months after the completion of the research project and remain available for a period of 3 years.

To whom data/document is available

Access is restricted to dental researchers, clinicians, and specialists who are actively involved in oral health research or dental practice. Applicants must provide proof of professional affiliation and relevant expertise.

Under which criteria data/document could be used

Data is to be used solely for academic and clinical research purposes related to oral health and dental treatments. Users must agree to confidentiality, not attempt re-identification of participants, and properly acknowledge the original study. Secondary analyses are permitted if aligned with the study’s scope and approved by the original investigators.

From where data/document is obtainable

Koumesh Journal of Medical Sciences, Semnan

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

The applicant submits a formal request to either Koumesh Journal of Medical Sciences or the Department of Research and Development via email or postal mail, specifying the data or documents they need. Once the request is received, the responsible department will review the application and verify the eligibility of the requested data/documentation. After verification, the department will respond to the applicant, confirming the availability of the requested data/documentation and the estimated time for delivery. The data or documentation will be sent to the applicant by email or postal mail, depending on the applicant’s preference. The entire process typically takes 5-7 business days, but it may vary depending on the complexity of the request.

Comments