# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 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
**City**
Semnan
**Province**
Semnan
**Postal code**
3518794431
**Phone**
+98 912 257 3961
**Email**
Mona_121360@yahoo.com

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Semnan University of Medical Sciences
**Full name of responsible person**
Dr. Ali Rashidipour
**Street address**
Headquarters of Semnan University of Medical Sciences and Health Services, Basij Boulevard, Semnan, Semnan Province
**City**
Semnan
**Province**
Semnan
**Postal code**
3518794431
**Phone**
+98 23 3332 4700
**Email**
Rashidy-Pour@semums.ac.ir
**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
**Street address**
Semnan Dental School, 17 Shahrivar Boulevard, Semnan
**City**
Semnan
**Province**
Semnan
**Postal code**
3518794431
**Phone**
+98 23 3332 4700
**Email**
Mona_121360@yahoo.com

## Person responsible for scientific 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

**Street address**

Semnan Dental School, 17 Shahrivar Boulevard, Semnan

**City**

Semnan

**Province**

Semnan

**Postal code**

3518794431

**Phone**

002333324700

**Email**

Mona_121360@yahoo.com

## Person responsible for updating data

**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

**Street address**

Semnan Dental School, 17 Shahrivar Boulevard, Semnan

**City**

Semnan

**Province**

Semnan

**Postal code**

3518794431

**Phone**

+98 23 3332 4700

**Email**

Mona_121360@yahoo.com

## 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**