

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### evaluation effect of diaphragmatic breathing on reducing pain and anxiety during anesthetic injection in children

#### Protocol summary

##### Study aim

This clinical trial study was conducted to determine the effect of diaphragm intubation on the amount of anxiety and pain in the course of dental anesthesia in children 6-12 years old

##### Design

In this research, 80 patients with inclusion criteria who come to the Department of Pediatrics at the Faculty of Dentistry are selected. Then, patients were not randomly divided into two control and intervention groups, and a code was allocated to each one of them.

##### Settings and conduct

In study in the Department of Pediatrics at the Faculty of Kerman Dentistry school. patient selected and divided into 2 groups A and B. All selected patients will receive prophylaxis and fluoride therapy at the first session. For group A, in first visit, the Diaphragmic Breathing is performed before the injection, and the third session without Diaphragmic Breathing only with the usual methods of control of the injection. for group B, in third session, Diaphragmic Breathing is performed before the injection And in the second session only with the usual methods of behavioral control of injection is done. During the Diaphragmic Breathing, the assistant that responsible for filling the questionnaire and it is supposed to be blind will not be present. After Diaphragmic Breathing, questionnaire is completed By the blind dental assistant.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 6 to 12 years : There are two rotatable toothpastes that can be repaired under local anesthesia in the jaw. Dental work must be done on two teeth and finish in a session: There is no history of a specific illness, and already should be health: Having an artificial intelligence: According to the approval of the parents, the patient refuses to go to the dental office for fear of anxiety and postpone the treatment : The patient is subject to Frankl's 2 and 3 standards . exclusion criteria : The child is fully cooperative or fully

uncooperative (Frankl 1 and 4) : The presence of medical problems and certain diseases: Talking in an inaudible language for the therapist : Sensitization : Use of any kind of delicacies 48 hours before the injection

##### Intervention groups

In the intervention group, along with routine behavioral control methods, Diaphragmic breathing will be done In this way, the child is asked to lie on the unit so that the knees bend slightly. The patient closes his eyes and calms his mind and does not pay attention to anything other than the therapist's words. The muscles of the face, arms and legs, and your body abandon. Put one hand on the chest and the other on the abdomen. By counting 1,2,3,4, the dentist calls the child to slowly breathe his breath through the nose through the nose. So that the hand on the abdomen is raised and the hand that is on the chest is fixed. Hold 1.2 with a breath in your abdomen, Subsequently, by counting 1,2,3,4 remove the breath slowly from the inside of the mouth so that the hand raised on the abdomen will return to its original state. He is asked when he wants to exhale his breath, imagine he wants to move a feather in the air and tell himself to be calm. We ask the child to take a breath at the time of taking care of which hand most moves? Try to send the air further into the abdomen to make it look like a balloon filled with air and then slowly push on your abdomen and empty the air. After the child learned the breathing technique, the diaphragmic breathing process continues for 5 to 3 minutes. In control group, only conventional behavioral control methods are performed.

##### Main outcome variables

Anxiety: Pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170722035212N2**

Registration date: **2017-12-30, 1396/10/09**

Registration timing: **registered\_while\_recruiting**

Last update: **2017-12-30, 1396/10/09**  
Update count: **0**

**Registration date**  
2017-12-30, 1396/10/09

**Registrant information**

**Name**  
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**Recruitment status**  
**Recruitment complete**

**Funding source**  
kerman Universal of Medical Sciences

**Expected recruitment start date**  
2017-12-11, 1396/09/20

**Expected recruitment end date**  
2018-03-11, 1396/12/20

**Actual recruitment start date**  
empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
evaluation effect of diaphragmatic breathing on reducing pain and anxiety during anesthetic injection in children

**Public title**  
The effect of diaphragmatic breathing on reducing pain and anxiety during anesthetic injection

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
Age 6 to 12 years There are two rotatable toothpastes that can be repaired under local anesthesia in the jaw. (Dental work must be done on two teeth and finish in a session) There is no history of a specific illness, and already should be health Having an artificial intelligence According to the approval of the parents, the patient refuses to go to the dental office for fear of anxiety and postpone the treatment The patient is subject to Frankl's 2 and 3 standards .

**Exclusion criteria:**  
The child is fully cooperative or fully uncooperative (Frankl 1 and 4) The presence of medical problems and certain diseases Talking in an inaudible language for the therapist Sensitization Use of any kind of delicacies 48 hours before the injection

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

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**

- Care provider
- Data analyser

**Sample size**  
Target sample size: **80**

**Randomization (investigator's opinion)**  
Not randomized

**Randomization description**  
Sampling will be inaccurately purposeful. In this way, one day per week will be screened and selected from patients referring to 80 patients who have criteria for entry And after giving a code to each patient, The codes will be placed in a sealed envelope And will be selected in random order. The choices will be made by the dental assistant who will be blind.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
Participants were divided into two groups by the researcher. The anesthetic intervention was performed by the researcher. The questionnaire was filled by a assistant dentist who was blind and after informed consent was obtained from the patient. The counselor does not know which patient is in the group.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**  
0

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**  
kerman University of Medical Sciences

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Kerman University of Medical Sciences

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**Postal code**  
0

**Approval date**  
2016-06-18, 1395/03/29

**Ethics committee reference number**  
IR.KMU.REC.1395.100

## Health conditions studied

### 1

#### Description of health condition studied

Anxiety

#### ICD-10 code

F40

#### ICD-10 code description

Phobic anxiety disorders

### 2

#### Description of health condition studied

pain

#### ICD-10 code

F45.4

#### ICD-10 code description

Pain disorders related to psychological factors

## Primary outcomes

### 1

#### Description

Anxiety

#### Timepoint

Ten minutes after intervention

#### Method of measurement

MCDAS questionnaire

### 2

#### Description

Pain

#### Timepoint

After dental treatment

#### Method of measurement

Wong baker Scale

## Secondary outcomes

### 1

#### Description

Score relaxation during treatment

#### Timepoint

Beginning of study, fourteenth day

#### Method of measurement

MCDASF questionnaire

### 2

#### Description

Score decrease of pain during treatment

#### Timepoint

Beginning of study, fourteenth day

#### Method of measurement

Wong Bakers Faces questionnaire, Sound-Eye-Motor scale

## Intervention groups

### 1

#### Description

Perform Diaphragmi Brething in intervention

#### Category

Behavior

### 2

#### Description

without perform Diaphragmi Breathing in the control

#### Category

Behavior

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Department of Pediatrics, School of Dentistry ,  
kerman

##### Full name of responsible person

Masume Danesh

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Department of Research and Technology of Kerman  
University of Medical Sciences

##### Full name of responsible person

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**Grant name**  
0

**Grant code / Reference number**  
0

**Is the source of funding the same sponsor organization/entity?**  
Yes

**Title of funding source**  
Department of Research and Technology of Kerman 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

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available