Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 inclucion criteria who come to the Departmwnt 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 scool. 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 Breathin 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 allready 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, Diaphragmatic 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 diaphragmatic breathing process continues for 5 to 3 minutes. In control group, only conventional behavioral control methods are performed.

Main outcome variables

Anxity؛ 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

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Name of organization / entity
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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 allready 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

Street address
Kerman University of Medical Sciences

City
kerman

Province
Kerman

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 questuionaire

2

Description
Pain
Timepoint
After dental treatment
Method of measurement
Wong baker Scale

Secondary outcomes

1

Description
Score relaxation during treatment
Timepoint
Biginning of study, fourteenth day
Method of measurement
MCDASF questionaire

2

Description
Score decrease of pain during treatment
Timepoint
Biginning of study, fourteenth day
Method of measurement
Wong Bakers Faces questionaire, 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
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Sponsors / Funding sources

1

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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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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