

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### The effect of breathing exercise using bubble blower on anxiety, behaviour and pain during inferior alveolar nerve block in children aged 7 to 10 years

#### Protocol summary

Anxiety ; Pain ; Behaviour

##### Study aim

Evaluation of the effect of breathing exercise using bubble blower on anxiety, behaviour and pain during inferior alveolar nerve block in children aged 7 to 10 years.

##### Design

Clinical trial with cross over design, with simple randomization without blinding with a sample size of 40

##### Settings and conduct

The study comprises two groups: 1 and 2; in the group 1 the breathing exercise is started a week before the the first pulp therapy visit, also it is used immediately before and during the injection. in the second visit the routine injection is done. in the group 2; in the first pulp therapy visit the routine injection is done. but the breathing exercise is started a week before the the second pulp therapy visit, also it is used immediately before and during the injection. Each group is divided to two subgroups : A and B; in the subgroup A right mandibular quadrant is treated in the first pulp therapy visit and left mandibular quadrant is treated in the second pulp therapy visit. it will be the opposite in the subgroup B.

##### Participants/Inclusion and exclusion criteria

Children with grade 3,4 or 5 of FIS who require bilateral pulp therapy of mandibular primary molars

##### Intervention groups

1. Control Group: routinely inferior alveolar nerve block with topical anaesthetic gel  
2. Intervention group: inferior alveolar nerve block with topical anaesthetic gel and breathing exercise during injection. in this exercise, the child must inhale deep breaths from the stomach and slowly exhale into a commercial bubble blower to make a big bubble. this exercise must be done 4-5 times a day one week before the pulp therapy using the bubble blower. it is repeated 4 times before the injection with the toy and during the injection without.

##### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191002044953N2**

Registration date: **2020-06-03, 1399/03/14**

Registration timing: **prospective**

Last update: **2020-06-03, 1399/03/14**

Update count: **0**

##### Registration date

2020-06-03, 1399/03/14

##### Registrant information

##### Name

Nahid Maghsoudi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3781 1631

##### Email address

nahidmaghsoudi@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-09-28, 1399/07/07

##### Expected recruitment end date

2021-02-18, 1399/11/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

The effect of breathing exercise using bubble blower on anxiety, behaviour and pain during inferior alveolar nerve block in children aged 7 to 10 years

**Public title**

The effect of breathing exercise using bubble blower on anxiety, behaviour and pain during mandibular anaesthesia injection in children aged 7 to 10 years

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Healthy children without any history of local anaesthetic drugs allergy or learning disabilities Children with grade 3,4 or 5 of FIS who require bilateral pulp therapy of mandibular primary molars Children with capable of communication in Farsi Children not requiring emergency treatment Children without major psychologic disorders like Separation Anxiety Disorder, General Anxiety Disorder and Obsessive-Compulsive Disorder

**Exclusion criteria:**

Necrotic teeth Parental uncooperation

**Age**From **7 years** old to **10 years** old**Gender**

Both

**Phase**

N/A

**Groups that have been masked***No information***Sample size**Target sample size: **40**

More than 1 sample in each individual

Number of samples in each individual: **2**

Each patient consists of two samples which are right and left mandibular quadrants.

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization: Simple. Randomization unit: mandibular quadrant . Randomization tool: Statistical Software. For allocation concealment, the numbers in the software list are separately put into envelopes. For each patient in the first visit, a sealed envelop is used to determine whether the breathing exercise is going to be used in the first or second pulp therapy visit. Another sealed envelop is used in the first pulp therapy visit to determine the first quadrant(left or right) undergoing treatment.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Crossover

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Shahid Sadoughi University of Medical Sciences

**Street address**

Dahe Fajr Ave , Imam Reza Square , Dentistry Faculty

**City**

Yazd

**Province**

Yazd

**Postal code**

89148-15669

**Approval date**

2020-05-03, 1399/02/14

**Ethics committee reference number**

IR.SSU.REC.1399.024

**Health conditions studied****1****Description of health condition studied**

Dental pain

**ICD-10 code**

k08.8

**ICD-10 code description**

Toothache NOS

**2****Description of health condition studied**

Anxiety

**ICD-10 code**

F41.9

**ICD-10 code description**

Anxiety NOS

**Primary outcomes****1****Description**

Anxiety level in Facial Image Scale

**Timepoint**

In the begining of the study in the first visit, also in both pulp therapy visits before the anasthesia injection.

**Method of measurement**

Facial Image Scale

**Secondary outcomes****1****Description**

Pulse rate  
**Timepoint**  
5 minutes before and after and during anaesthesia injection in pulp therapy visits  
**Method of measurement**  
Pulse rare measurement

## 2

**Description**  
Pain  
**Timepoint**  
Immediately after anaesthesia injection in pulp therapy visits  
**Method of measurement**  
Subjective evaluation using Wong Baker Facial Pain Scale

## 3

**Description**  
Pain  
**Timepoint**  
During anaesthesia injection in pulp therapy visits  
**Method of measurement**  
Objective evaluation using Face Leg Activity Cry Consolobility Scale

## 4

**Description**  
Behaviour  
**Timepoint**  
During anaesthesia injection in pulp therapy visits  
**Method of measurement**  
Objective evaluation using Frankl Behaviour Rating Scale

## Intervention groups

### 1

**Description**  
Intervention group: practising the breathing exercise one week before the pulp therapy with bubble blower, four times practice before the injection and repeating the exercise during injection(without blower)  
**Category**  
Treatment - Other

### 2

**Description**  
Control group: Routinely inferior alveolar nerve block injection using topical anaesthetic gel.  
**Category**  
Treatment - Other

## Recruitment centers

### 1

**Recruitment center**  
Name of recruitment center

Dentistry Faculty of Shahid Sadoughi University of Medical Sciences  
**Full name of responsible person**  
Nahid Maghsoudi  
**Street address**  
Dahe Fajr Ave , Imam Reza Square  
**City**  
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nahidmaghsoudi@yahoo.com

## Sponsors / Funding sources

### 1

**Sponsor**  
**Name of organization / entity**  
Yazd University of Medical Sciences  
**Full name of responsible person**  
Masoud Mirzaei  
**Street address**  
No. 2, Shahid Sadoughi Ave., Bahonar Square., Yazd, Iran  
**City**  
Yazd  
**Province**  
Yazd  
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8916978477  
**Phone**  
+98 35 3724 0171  
**Email**  
masoud\_mirzaei@hotmail.com  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Yazd 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

Yazd University of Medical Sciences

**Full name of responsible person**

Nahid Maghsoudi

**Position**

Resident of pediatric dentistry

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

**Street address**

No. 1, Imam Reza Blvd., Imam Reza Square., Yazd,  
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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)**

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**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Undetectable information such as age, sex and previous dental treatments history will be published. Study outcomes will also be published, including changes in pulse rate and data regarding Facial Image Scale, Wong-Baker Facial Pain Scale, Face Leg Activity Cry Consolability Scale and Frankle behaviour rating scale .

**When the data will become available and for how long**

9 months after publication

**To whom data/document is available**

The data are only available for investigators working in academic and scientific institutions.

**Under which criteria data/document could be used**

Use of this data is permitted for systematic review and meta-analysis. Similar clinical trials can also use the data to criticize the present study and its results in their Discussion.

**From where data/document is obtainable**

1. Send an email to nahidmaghsoudi@yahoo.com 2. Send an email to zbahrololoom@yahoo.com 3. Telephone Call with Dr. Zahra Bahrololoomi, No. 983536214257.

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

After the request via one of the three methods listed above, if the request matches the sharing information mentioned before, this information will be available to the applicant within one month.

**Comments**