

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### Comparison of the Effectiveness of Topical Anesthesia Gel and Relaxation Training Exercise on Pain Perception during Infiltration Injection in the Anterior Maxilla

#### Protocol summary

Registration timing: **prospective**

#### Study aim

Determination Pain Perception On During Infiltration Injection In the Anterior Maxilla In Relaxation Training Exercise Determination Pain Perception On During Infiltration Injection In the Anterior Maxilla In Topical Anesthetic Gel Comparison Pain Perception On During Infiltration Injection In the Anterior Maxilla In Relaxation Training Exercise And Topical Anesthetic Gel

Last update: **2019-12-14, 1398/09/23**

Update count: **0**

#### Registration date

2019-12-14, 1398/09/23

#### Registrant information

##### Name

Shahrzad Nematollahi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 66 4332 2071

##### Email address

sh.nematollahi.30@gmail.com

#### Design

Clinical Trial Without Control Group

#### Settings and conduct

Children In Kermanshah Dental School Was Applied Topical Anesthetic Gel Before Infiltration Injection In the Anterior Maxilla In 1Visit And After 3 Days Was Applied Bubble Breath Before Infiltration Injection in the Anterior Maxilla In The Other Side

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Participants/Inclusion and exclusion criteria

Good Systemic Health And Requiring Dental Treatment Under Maxillary Anterior Infiltration Anesthesia and written Informed Consent from the Parents and Written Informed Assent from the Children : acute pain And Requiring Emergency Dental Treatment And Illness Requiring Special Medical Care

#### Expected recruitment start date

2019-12-31, 1398/10/10

#### Expected recruitment end date

2020-02-28, 1398/12/09

#### Intervention groups

Comparison Effect Of Banzocaine Gel And Relaxation Training Exercise In Children Before Injection In the Anterior Maxilla

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Main outcome variables

Severity Of Pain

#### Trial completion date

empty

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191121045465N1**

Registration date: **2019-12-14, 1398/09/23**

#### Scientific title

Comparison of the Effectiveness of Topical Anesthesia Gel and Relaxation Training Exercise on Pain Perception during Infiltration Injection in the Anterior Maxilla

#### Public title

Comparison of the Effectiveness of Topical Anesthesia

Gel and Relaxation Training on Pain Injection

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

Good Systemic Health Requiring Dental Treatment Under Maxillary Buccal Infiltration Anesthesia Following Written Informed Consent from the Parents and Written Informed Assent from the Children

### Exclusion criteria:

presenting with acute pain suffering from any illness requiring special medical care requiring emergency dental treatment

## Age

From **10 years** old to **12 years** old

## Gender

Both

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **50**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Single

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

##### Street address

Taleghani Dormitory

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

68618-41619

#### Approval date

2019-11-05, 1398/08/14

#### Ethics committee reference number

IR.KUMS.REC.1398.760

## Health conditions studied

### 1

#### Description of health condition studied

The study on the effect of topical anesthesia gel and relaxation training exercise on pain perception during infiltration injection in the anterior maxilla

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Severity of Pain

#### Timepoint

Application of Topical Anesthesia Gel And After 3 Days  
Application Relaxation Training Exercise

#### Method of measurement

Visual Analogue Scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group:in Visit 1 Application Topical Anesthesia Gel With Sterile Cotton Applicator 2Minutes at the Height of the Mucobuccal fold over the Target Tooth Before infiltration injection in the anterior maxilla . in Visit 2 Use of the Bubble Breath Exercise as a Relaxation Strategy Before infiltration injection

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Kermanshah Dental School

##### Full name of responsible person

Shahzad Nematollahi

##### Street address

Taleghani Dormitory

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

68618\_41619

##### Phone

+98 66 4332 2071

##### Email

sh.nematollahi.30@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Frid Najafi

**Street address**

Kermanshah University of Medical Sciences, Building 2, Shahid Beheshti Boulevard, Kermanshah, Iran

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

68618\_41619

**Phone**

+98 83 3836 0016

**Email**

farid\_n32@yahoo.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Kermanshah 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**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Shahrzad Nematollahi

**Position**

Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Dentistry

**Street address**

Taleghani Dormitory

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

68618\_41619

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+98 66 4332 2071

**Email**

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Shahrzad Nematollahi

**Position**

Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

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Kermanshah University of Medical Sciences

**Full name of responsible person**

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A Level or less

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**Phone**

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**Email**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

No More Information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable