Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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

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

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

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

Main outcome variables
Severity Of Pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191121045465N1**
Registration date: **2019-12-14, 1398/09/23**
Registration timing: **prospective**

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

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-31, 1398/10/10

Expected recruitment end date
2020-02-28, 1398/12/09

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

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

Shahrzad Nematollahi

Street address

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City

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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
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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
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Person responsible for updating data

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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