Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Evaluation of sweet aromatherapy effect on pain level of maxillary primary molars infiltration anesthesia in 7-9 years old children

Protocol summary

Study aim

evaluation the effect of sweet odor aromatherapy in pain level of maxillary molars infiltration in children 7-9 years old

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized on 32 patients, a simple randomization method with a sealed envelope will be used for randomization.

Settings and conduct

Children aged 7-9 years in the pediatric ward of Qazvin Dental School who need maxillary molar infiltration included due to inclusion and exclusion criteria. Injection in the first intervention group is done in the room with saturated sweet smell, in the second intervention group, it is done at the same time with exposure to sweet smell (with a higher saturation than the first intervention group)and in the control group in an odorless environment. The evaluator encounters the child after preparation (evaluator blinding) and the statistical analyzer receives the data in group codes (analyzer blinding)

Participants/Inclusion and exclusion criteria

Children aged 7-9 years who need infiltration of maxillary primary molars, who are healthy and cooperative, are included in the study and are excluded from the study in case of any allergies or problems with sweets, smelling disorders or acute dental conditions.

Intervention groups

In the first session, the children receive brushing and fluoride therapy in order to shape their behavior, and in the next session, after using the tell-show-do technique, Injection in the first intervention group is done in the room with saturated sweet smell, in the second intervention group, it is done at the same time with exposure to sweet smell (with a higher saturation than the first group) and in the control group in an odorless environment.

Main outcome variables

Objective evaluation according to FLACC criteria; Subjective evaluation according to Wong Baker criteria; Heart rate; Degree of blood oxygen saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180104038218N3**
Registration date: **2022-04-09, 1401/01/20**
Registration timing: **prospective**

Last update: **2022-04-09, 1401/01/20**
Update count: **0**

Registration date

2022-04-09, 1401/01/20

Registrant information

Name

Razieh Jabbarian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3335 3061

Email address

r.jabbarian@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-30, 1401/02/10

Expected recruitment end date

2022-07-01, 1401/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of sweet aromatherapy effect on pain level of maxillary primary molars infiltration anesthesia in 7-9 years old children

Public title

Evaluation of the effect of sweet odor on pain level of upper jaw anesthesia in children 7-9 years old

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

children 7-9 years old requiring maxillary molar infiltration systemic and developmental health Positive behavior according to Frankle classification (cooperative and without resistance to treatment) Do not eat or drink anything for at least one hour before the injection

Exclusion criteria:

ear, nose, throat disorders allergy, sinusitis or tonsillitis current cold or any other smelling disorder The presence of spontaneous / nocturnal pain or abscess in the desired tooth Pain, inflammation and any other problems in the injection site child's previous dental experiment

Age

From **7 years** old to **9 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done in blocked randomization method and blocking and sequencing of samples will be done with random allocation software; The names of the groups are then placed in envelopes from 1 to 48 and placed in a box, respectively. The researcher who will make the random assignment will not be aware of the contents of the envelopes and the contents of the envelopes indicate the study groups (anesthesia in the saturated environment of odor, sudden exposure to odor and control) and after ensuring that the sample enters the research and Obtaining written consent, the first envelope is removed in order and placed in one of the study groups according to the content of the envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description

Outcome assessment is performed by a person other than the researcher and clinical caregiver and because he / she is present at the patient's bedside after the intervention, he / she is blind to the received intervention. The grouping results of each sample are delivered to the statistical analyzer in the form of numbers.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Qazvin University of Medical Sciences

Street address

Bahonar Boulvard

City

Qazvin

Province

Qazvin

Postal code

3419759811

Approval date

2022-01-23, 1400/11/03

Ethics committee reference number

IR.QUMS.REC.1400.427

Health conditions studied

1

Description of health condition studied

injection in pediatric dentistry

ICD-10 code

G89.1

ICD-10 code description

Acute pain, not elsewhere classified

Primary outcomes

1

Description

objective level of pain

Timepoint

after completion of anesthesia

Method of measurement

Face,leg,activity,crying,consolability (FLACC)

2

Description

subjective pain level

Timepoint

after injection completion

Method of measurement
Wong baker

3

Description
heart rate
Timepoint
before, during and after injection
Method of measurement
pulse oximeter

4

Description
oxygen saturation
Timepoint
before, during and after injection
Method of measurement
pulse oximeter

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the first session, children receive brushing and fluoride therapy to shape their behavior, and in the next session, after using the tell-show-do technique, they are injected with infiltration in the area of the maxillary molars. The intervention group is placed in a room saturated with a sweet smell during injection. The injection technique in all three groups was the same, first by applying a topical benzocaine gel (20%) to the mucosa for one minute and then a carpol of 8.1 ml of 2% lidocaine + epinephrine 1: 80000 (Daroupakhsh, Iran) and a needle. 25 mm with gauge 27 (Sirio, Italy). After pulling the mucus, a needle is inserted at a 45 degree angle of 1-2 mm into the mucosa and a few drops are injected. After aspiration, more progress is made and the injection is completed. All injections are given by one person.
Category
Treatment - Other

2

Description
Intervention group: In the first session, children receive brushing and fluoride therapy to shape their behavior, and in the next session, after using the tell-show-do technique, they are injected with infiltration in the area of the maxillary molars. The second intervention group is exposed to a sudden sweet odor(with a higher saturation than the first intervention group) just during the injection. The injection technique in all three groups was the same, first by applying a topical benzocaine gel (20%) to the mucosa for one minute and then a carpol of 8.1 ml of 2% lidocaine + epinephrine 1: 80000 (Daroupakhsh, Iran) and a needle. 25 mm with gauge 27 (Sirio, Italy). After pulling the mucus, a needle is inserted at a 45 degree angle of 1-2 mm into the mucosa and a few drops are injected. After aspiration, more progress is made and the injection is completed. All injections are given by one person.
Category
Treatment - Other

3

Description
Control group: In the first session, children receive brushing and fluoride therapy to shape their behavior, and in the next session, after using the tell-show-do technique, they are injected with infiltration in the area of the maxillary molars. The control group is placed in the injection room and is not exposed to any odor. The injection technique in both groups was the same, first by applying a topical benzocaine gel (20%) to the mucosa for one minute and then a carpol of 8.1 ml of 2% lidocaine + epinephrine 1: 80000 (Daroupakhsh, Iran) and a needle. 25 mm with gauge 27 (Sirio, Italy). After pulling the mucus, a needle is inserted at a 45 degree angle of 1-2 mm into the mucosa and a few drops are injected. After aspiration, more progress is made and the injection is completed. All injections are given by one person.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Qazvin university of medical sciences, faculty of dentistry
Full name of responsible person
Razieh Jabbarian
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person

Dr Mehdi Mirhashemi

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Qazvin 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
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Razieh Jabbarian

Position
assistant professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Razieh Jabbarian

Position
assistant professor

Latest degree
Specialist

Other areas of specialty/work
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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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available