Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Investigating the Effect of Lavender Aroma on Pain Levels, Anxiety, and Cooperation in Children Aged 7 to 10 During the Use of Conventional and Computerized Anesthesia: A Randomized Clinical Trial

Protocol summary

Study aim
The effect of lavender scent on pain level, anxiety, and cooperation of 7 to 10-year-old children during the use of conventional anesthesia and computer anesthesia: A randomized clinical trial.

Design
Random allocation using the block randomization method, so that with a total sample size of 72, there will be 9 blocks of 8. When a patient arrives, one of these blocks will be randomly selected and assigned to the desired group.

Settings and conduct
In the first session, children along with their parents entered an isolated room to familiarize themselves with the environment; only children with a Frankel score of 3 or 4 participated in the study. In the second session, the groups that received lavender aromatherapy, while the room was ventilated for the other groups, had their heart rate and oxygen saturation recorded before anesthesia. After the injection, vital signs, pain, and behavior of the children were measured and documented. In the third session, the groups continued with different anesthesia methods.

Participants/Inclusion and exclusion criteria
Children aged 7 to 10 years who require similar treatment on both sides of the lower jaw arch and have no history of allergy to lavender scent.

Intervention groups
Group 1: exposed to lavender received digital anesthesia in the second session and normal anesthesia in the following session. Group 2: exposed to lavender received normal anesthesia in the second session and digital anesthesia in the following session. Group 3: not exposed to lavender received digital anesthesia in the second session and normal anesthesia in the following session. Group 4: not exposed to lavender received normal anesthesia in the second session and digital anesthesia in the following session

Main outcome variables
Determining the mean heart rate, oxygen saturation and cooperation, anxiety, and pain scores after anesthesia injection.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250522065846N1**
Registration date: **2025-05-29, 1404/03/08**
Registration timing: **registered_while_recruiting**

Last update: **2025-05-29, 1404/03/08**
Update count: **0**

Registration date
2025-05-29, 1404/03/08

Registrant information

Name
Bahare Davvaz

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-05-24, 1404/03/03

Expected recruitment end date
2025-11-24, 1404/09/03

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the Effect of Lavender Aroma on Pain Levels, Anxiety, and Cooperation in Children Aged 7 to 10 During the Use of Conventional and Computerized Anesthesia: A Randomized Clinical Trial

Public title
Investigating the Effect of Lavender Aroma on Pain Levels, Anxiety, and Cooperation in Children Aged 7 to 10 During the Use of Conventional and Computerized Anesthesia: A Randomized Clinical Trial
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Children in the 7 to 10 year age range. Healthy children physically and mentally (without a history of serious physical or mental illnesses that may affect anxiety or pain perception). Children who demonstrate the ability to cooperate with the dentist in the initial evaluation (level 3 or 4 on the Frankl Behavior Rating Scale). Children who are in the moderate or mild range in the initial dental anxiety assessment. Participants who do not have a history of sensitivity or allergy to herbal scents, especially lavender. Children who require similar treatment on both sides of the lower jaw and require anesthesia with an alveolar nerve block injection. Children who, at the time of the study, are not taking sedatives, anti-anxiety medications, or painkillers that can affect anxiety or pain levels. Children with sufficient cognitive skills to complete the self-report scale. Parents or legal guardians must sign a written consent form for the child to participate in the study. Children who do not score above 25 on the SCARED questionnaire.
Exclusion criteria:
Children whose parents refuse to allow their child to participate in this study. Children with mental and physical disabilities. Children who have used NSAIDs, painkillers, or opioids in the past 8 hours. Children who did not attend after the second session.
Age
From **7 years** old to **10 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **72**
More than 1 sample in each individual
Number of samples in each individual: **2**
Group 1 (18 people): A group exposed to lavender scent, receiving digital anesthesia on one side in the second session and conventional anesthesia on the opposite side in the following session. Group 2 (18 people): A group exposed to lavender scent, receiving conventional anesthesia on one side in the second session and digital anesthesia on the opposite side in the following session. Group 3 (18 people): A group not exposed to lavender scent, receiving digital anesthesia on one side in the second session and conventional anesthesia on the opposite side in the following session. Group 4 (18 people): A group not exposed to lavender scent, receiving conventional anesthesia on one side in the second session and digital anesthesia on the opposite side in the following session.
Randomization (investigator's opinion)
Randomized
Randomization description
Random allocation of all individuals in groups (N=72) using the block randomization method, considering the sequence (AB, BA) for conventional anesthesia (A = with lavender fragrance, B = without lavender fragrance). Sequence (CD, DC) for computer-assisted anesthesia (C = with lavender fragrance, D = without lavender fragrance) is performed, considering a block size of 8. For this purpose, the randomizeBE package in R software is used.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the participants, the dentist, and the evaluator are blind to the type of anesthesia used.
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Zahedan University
Street address
Zahedan Faculty of Dentistry
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9817699693
Approval date
2025-05-17, 1404/02/27
Ethics committee reference number
IR.ZAUMS.REC.1404.058

Health conditions studied

1

Description of health condition studied
children anesthesia
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Cooperation: in children in dentistry refers to a child's ability to actively and calmly participate in dental treatment processes, such as examinations or anesthesia injections, without resistance or negative behaviors.2.4s
Timepoint
Assessment of cooperation after anesthesia injection
Method of measurement
based on Venham Clinical Cooperation Scale (VCCS)

2

Description
Pain: in pediatric dentistry refers to physical discomfort or distress caused by treatment procedures, such as anesthesia injections or dental treatments, which psychological and environmental factors can influence.4.8s
Timepoint
Assessment of pain after anesthesia injection
Method of measurement
based on Wong Baker index

3

Description
anxiety: An abnormal fear or unwarranted anxiety about visiting the dentist for dental treatment procedures is described.
Timepoint
Assessment of anxiety after anesthesia injection
Method of measurement
based on Venham Clinical Cooperation Scale (VCCS)

Secondary outcomes

1

Description
Heart rate: Heart rate is the number of heartbeats per minute, measured in beats per minute (bpm), indicating heart health or responses to factors like stress or anesthesia.
Timepoint
Measurement of heart rate before and after anesthesia injection.
Method of measurement
Finger pulse oximeter

2

Description
Oxygen saturation (SpO2) measures the percentage of hemoglobin bound to oxygen in the blood, assessed by a finger pulse oximeter, typically 95–100% in healthy individuals.
Timepoint
Measurement of pulse oximeter saturation before and after anesthesia injection.
Method of measurement
Finger pulse oximeter

Intervention groups

1

Description
Intervention group :Group 1: Exposed to lavender aromatherapy, receiving digital anesthesia on one side in the second session and conventional anesthesia on the opposite side in the third session.Group 2: Exposed to lavender aromatherapy, receiving conventional anesthesia on one side in the second session and digital anesthesia on the opposite side in the third session.Group 3: Not exposed to lavender aromatherapy, receiving digital anesthesia on one side in the second session and conventional anesthesia on the opposite side in the third session.Group 4: Not exposed to lavender aromatherapy, receiving conventional anesthesia on one side in the second session and digital anesthesia on the opposite side in the third session.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Zahedan Faculty of Dentistry
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Zahedan 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
Zahedan University of Medical Sciences
Full name of responsible person
Bahare Davvaz
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is 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

Title and more details about the data/document

Most data can potentially be shared after de-identifying individuals.

When the data will become available and for how long

Start of the access period is 6 months after publication of the results.

To whom data/document is available

It will only be accessible to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Any type of analysis on the delivered data is permitted.

From where data/document is obtainable

Via email at baharedvz@gmail.com

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

It can request via email.

Comments