# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 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**

**Country**
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**
Bahare Davvaz
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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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## 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)**
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**