Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigation of The Effect of Lavender Oil Inhalation on Anxiety, Heart Rate And Blood Pressure of Children's Dental Treatment

Protocol summary

Study aim
Comparison of the effect of lavender oil inhalation with the control group on blood pressure, anxiety, and heart rate after anesthetic injection.

Design
Randomized controlled clinical trial with a control group, single-blind, parallel group, phase 3 conducted on 46 patients, Stratified block randomization with SPSS

Settings and conduct
Patients presenting to the Urmia Faculty of Dentistry who meet the study inclusion criteria will be stratified by gender and randomly allocated to intervention and control groups. In the intervention group, lavender oil will be inhaled before anesthetic injection, and distilled water in the control group. The principal investigator will be blinded to group allocation. Anxiety level, heart rate, and blood pressure will be measured before and after the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: healthy children with healthy systemic condition; patients aged 7 to 9 years; children requiring restorative treatment of a unilateral mandibular permanent first molar. Exclusion criteria: patients with previous dental treatment; dental pain

Intervention groups
The intervention group receives inhalational lavender oil aroma (Essential oil will be obtained by hydrodistillation of dried plant parts and subsequently purifies with anhydrous sodium thiosulfate; Prepared at the Faculty of Pharmacology, Urmia University of Medical Sciences) 60 minutes before the start of dental procedures (anesthetic injection); 0.5 mL of the oil is dripped onto a 7.5 × 7.5 cm gauze and placed 20 cm from the child’s nose for 15 minutes. Control group: The same protocol will be followed, but with distilled water dripped onto the sterile gauze.

Main outcome variables
Anxiety; blood pressure; heart rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220107053654N2**
Registration date: **2026-07-14, 1405/04/23**
Registration timing: **retrospective**

Last update: **2026-07-14, 1405/04/23**
Update count: **0**

Registration date
2026-07-14, 1405/04/23

Registrant information

Name
Maryam Khosrozadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 4279 4000

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-10-23, 1404/08/01

Expected recruitment end date
2026-01-21, 1404/11/01

Actual recruitment start date
2025-11-01, 1404/08/10

Actual recruitment end date
2026-02-09, 1404/11/20

Trial completion date
2026-02-09, 1404/11/20

Scientific title

Investigation of The Effect of Lavender Oil Inhalation on Anxiety, Heart Rate And Blood Pressure of Children's Dental Treatment

Public title
Effect of Lavender Oil on The Anxiety, Heart Rate And Blood Pressure of Children
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
children with healthy systemic condition Age of patients between 7 and 9 years Children requiring restorative treatment of the mandibular permanent first molar on one side
Exclusion criteria:
Patients with prior dental treatment Children with symptoms of dental pain
Age
From **7 years** old to **9 years** old
Gender
Both

Phase
3
Groups that have been masked

- Care provider
- Investigator

Sample size
Target sample size: **46**
Actual sample size reached: **46**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to control for the confounding effect of gender on anxiety levels, stratified randomization will be used. For this purpose, participants will first be divided into two strata (girls and boys) based on gender. To allocate participants to the intervention and control groups, a random sequence will be generated using SPSS software, taking into account random blocks of a size of 4. The unit of randomization will be the individual participant. To ensure allocation concealment, the generated sequence will not be available to the main investigator, and sealed envelopes will be used so that the allocation of each individual to the groups will be performed by a person who does not play a role in the screening and enrollment process of the participants. Finally, 12 girls and 11 boys will be entered into the study in each group.
Blinding (investigator's opinion)
Single blinded
Blinding description
The researcher and the treating dentist will not be aware of the patient’s exposure to the aroma. The implementation of the intervention will be performed by another student who will have no role in data collection or data analysis. Following completion of the intervention, the room will be ventilated in order to maintain the blinding conditions, and subsequently the dental treatment will be initiated. In the control group, all procedures will be performed similarly, with the difference that sterile distilled water will be used on the gauze instead of lavender essence.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Urmia University of Medical Sciences
Street address
Urmia University of Medical Sciences, Emergency Alley, Resalat St., Urmia, Iran
City
Urmia
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West Azarbaijan
Postal code
5714783734
Approval date
2025-10-22, 1404/07/30
Ethics committee reference number
IR.UMSU.REC.1404.355

Health conditions studied

1

Description of health condition studied
local anesthetic injection
ICD-10 code
T41.3X5
ICD-10 code description
Adverse effect of local anesthetics

Primary outcomes

1

Description
Anxiety
Timepoint
During local anesthetic administration; 60 minutes after the intervention.
Method of measurement
Facial rating scale

2

Description
Heart rate
Timepoint
Once before receiving the inhaled aroma; and again 1

minute after completion of the local anesthetic injection.

Method of measurement

Digital sphygmomanometer

3

Description

Systolic blood pressure

Timepoint

Once before receiving the inhaled aroma; and again 1 minute after completion of the local anesthetic injection.

Method of measurement

Digital sphygmomanometer

4

Description

Diastolic blood pressure

Timepoint

Once before receiving the inhaled aroma; and again 1 minute after completion of the local anesthetic injection.

Method of measurement

Digital sphygmomanometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Receives inhalational lavender oil aroma (Essential oil will be obtained by hydrodistillation of dried plant parts and subsequently purifies with anhydrous sodium thiosulfate; Prepared at the Faculty of Pharmacology, Urmia University of Medical Sciences) 60 minutes before the start of dental procedures (anesthetic injection); 0.5 mL of the oil is dripped onto a 7.5 × 7.5 cm gauze and placed 20 cm from the child’s nose for 15 minutes.

Category

Treatment - Drugs

2

Description

Control group: Distilled water was administered by inhalation 60 minutes before the start of the dental procedure (local anesthetic injection). A total of 0.5 mL of distilled water was applied to a 7.5 × 7.5 cm gauze pad, which was placed 20 cm from the child's nose for 15 minutes.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dentistry Faculty of Urmia University of Medical Sciences

Full name of responsible person

Maryam Khosrozadeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Saber Gholizadeh

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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

Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Maryam Khosrozadeh
Position
Assistant Professor of Pediatric Dentistry
Latest degree
Specialist
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)
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