Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Studying the effect of lavender and rose Essential oil on preoperative anxiety in children undergoing adenotonsillectomy surgery

Protocol summary

Study aim

this study was designed to investigate and compare the effect of inhaled aromatherapy using lavender, rose, and a combination of lavender and rose essential oils on anxiety before surgery in patients undergoing adenotonsillectomy.

Design

A controlled, parallel-group, double-blind, randomized, phase 3 clinical trial on 120 patients. sealedenvelope.com was used for randomization.

Settings and conduct

The study location is Matini Hospital in Kashan.in the inpatient ward, the researcher drops 5 drops of the aromatic product prepared for each patient (blind to the type of essential oil) according to the color code and using a dropper on a non-absorbent tissue and attaches it to the patient's collar at a distance of twenty centimeters from the participants' noses. It is recommended that they inhale it normally for 15 minutes. After fifteen minutes, upon entering the operating room and separating from their parents, and then during the anesthesia process, the Yale Anxiety Questionnaire will be completed by an independent researcher who is unaware of the type of essential oil, and physiological indicators will also be measured and recorded.

Participants/Inclusion and exclusion criteria

 No history of previous surgery or anesthesia No history of allergic rhinitis, No history of respiratory and skin allergies in the child and mother, No chronic pain in the child No long-term history of digestive problems Accompanying a first-degree parent Informed consent to participate in the study Exclusion criteria include the following: Lack of cooperation during the study. Occurrence of allergic symptoms during the intervention process

Intervention groups

Aromatherapy group with lavender essential oil
Aromatherapy group with rose essential oil
Aromatherapy group with combined lavender and rose essential oil Control group

Main outcome variables

Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240419061523N3**
Registration date: **2026-04-29, 1405/02/09**
Registration timing: **prospective**

Last update: **2026-04-29, 1405/02/09**
Update count: **0**

Registration date

2026-04-29, 1405/02/09

Registrant information

Name
Nahid Norouzi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 31 5510 3142
Email address
norouzi-na@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-05-22, 1405/03/01

Expected recruitment end date

2026-09-23, 1405/07/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Studying the effect of lavender and rose Essential oil on preoperative anxiety in children undergoing adenotonsillectomy surgery

Public title
The effect of aromatherapy with lavender and rose essential oils on preoperative anxiety in children undergoing adenotonsillectomy surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
 Children who are candidates for tonsillectomy No history of previous surgery or anesthesia No history of allergic rhinitis No history of respiratory or skin allergies in the child or mother No chronic pain in the child No long-term history of digestive problems Accompanying a first-degree parent Informed consent to participate in the study
Exclusion criteria:
Age
From **3 years** old to **10 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
For randomization, a member of the research team, acting as a nutritionist, will use four color labels, red, orange, yellow, and blue, to code each bottle containing the essential oil. Each bottle will then be placed inside a box, and each box will be labeled with the same color label according to the color of the bottle. Participants will be randomly assigned to the treatment or placebo group using balanced block randomization (https://www.sealedenvelope.com/trials/) and color-coded.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants, healthcare personnel (physicians, operating room nurses) responsible for patient care, and data collectors who assess the outcome are kept blind to the type of essential oil used.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Kashan University of Medical Sciences
Street address
Pezeshk Blvd, Qotb–e Ravandi Blvd, Kashan
City
Kashan
Province
Isfehan
Postal code
8715973474
Approval date
2026-03-15, 1404/12/24
Ethics committee reference number
IR.KAUMS.NUHEPM.REC.1404.075

Health conditions studied

1

Description of health condition studied
Anxiety before surgery
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Anxiety score on the Modified-Yale preoperative anxiety scale (YPAS) questionnaire
Timepoint
Measuring anxiety after the start of the intervention and before entering the operating room
Method of measurement
Preoperative anxiety will be measured using the standardized Modified Yale Preoperative Anxiety Scale (m-YPAS) questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: Aromatherapy group with lavender essential oil

Category

Prevention

2

Description

Second intervention group: Aromatherapy group with rose essential oil

Category

Prevention

3

Description

Third intervention group: Aromatherapy group with combined lavender and rose essential oil

Category

Prevention

4

Description

Control group: received placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Matini Hospital

Full name of responsible person
Nahid Norouzi

Street address
Kashan, Amir Kabir Street, Matini Hospital

City
Kashan

Province
Isfehan

Postal code
8719674591

Phone
+98 31 5534 2020

Email
matinihospital@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Dr. Gholamali Hamidi

Street address
Kashan - 5th km. of Qotb Ravandi Boulevard - Kashan University of Medical Sciences - Research Office

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Province
Isfehan

Postal code
8715988141

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Email
research@kaums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Kashan 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
Kashan University of Medical Sciences

Full name of responsible person
Nahid Norouzi

Position
instructor

Latest degree
Master

Other areas of specialty/work
Operating room technology

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Pezeshk Blvd, Qotb–e Ravandi Blvd, Kashan, Iran

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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is 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
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data is potentially shareable after de-identifying individuals.

When the data will become available and for how long
Access period starts 6 months after results are published.

To whom data/document is available
Our data will only be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used
In order to conduct scientific research

From where data/document is obtainable
Please send a message to the following email address: n.noroozi1992@yahoo.com

What processes are involved for a request to access data/document
The required files will be sent immediately after receiving the applicant's message and providing documentation regarding the research work.

Comments