Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison the effect of lavender and rose aroma on children's pain and anxiety after surgery: A controlled randomized clinical trial.

Protocol summary

Study aim
Determining and comparing the effects of lavender and rose scents on pain and anxiety after pediatric surgery.

Design
This study is a randomized clinical trial. The sample size was calculated using Gpower software and considering the values obtained from similar studies and considering the effect size of 0.61, type I error of 0.05, power of 80%, and predicted sample attrition rate of 10%. The final sample size for the three control and intervention groups with lavender and rose flower scent was 111 people (37 people in each group).

Settings and conduct
This study will be conducted in the surgical ward of Mardani Azar Children's Hospital. Children who meet the inclusion criteria will be included in the study using convenience method and informed consent forms will be obtained from their parents. Then, eligible children will be assigned to one of three control, lavender, and rose groups using a random block of four and six.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 7-12 years, appendectomy surgery, no psychiatric problems based on medical records, no asthma and allergic rhinitis based on questions from parents. Exclusion criteria: Need for oxygen after surgery, need for intensive care after surgery.

Intervention groups
Intervention group1: Using lavender scent to manage children's pain and anxiety Intervention group2: Using rose scent to manage children's pain and anxiety Control group: Using distilled water to manage children's pain and anxiety

Main outcome variables
During this study, the effect of the type of aromatherapy as an independent variable on pain intensity (primary outcome) and anxiety (secondary outcome) as dependent variables after surgery will be examined.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250726066642N3**
Registration date: **2026-04-22, 1405/02/02**
Registration timing: **prospective**

Last update: **2026-04-22, 1405/02/02**
Update count: **0**

Registration date
2026-04-22, 1405/02/02

Registrant information

Name
Fatemeh Ghorbani

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
2026-05-15, 1405/02/25

Expected recruitment end date
2026-08-16, 1405/05/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison the effect of lavender and rose aroma on children's pain and anxiety after surgery: A controlled randomized clinical trial.

Public title
The Effect of Aromatherapy on Pain and Anxiety
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age: 7 to 12 years old Underwent appendectomy surgery No history of psychological disorders based on the child’s medical record. No history of asthma or allergic rhinitis based on parental report.
Exclusion criteria:
Need for post-operative oxygen therapy Patient deterioration post-surgery requiring intensive care
Age
From **7 years** old to **12 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **111**
Randomization (investigator's opinion)
Randomized
Randomization description
Samples will be selected from all patients admitted to the surgical ward who have undergone appendectomy using the convenience sampling method. Then, eligible children will be randomly assigned using a block randomization method (four and six blocks) into one of three groups (lavender scent, Damask rose scent, and control). Opaque, sealed envelopes will be used to conceal the sequence of children's allocation to the groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, blinding of the principal investigator and intervention recipients was not achievable. However, the data analyst (research assistant) is blinded to the group allocation of the children.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Central Building No. 2, Third Floor, Vice-Chancellery for Research and Technology, Tabriz University of Medical Sciences, Golgasht Street, Tabriz, Iran
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Approval date
2026-03-16, 1404/12/25
Ethics committee reference number
IR.TBZMED.REC.1404.870

Health conditions studied

1

Description of health condition studied
pain and anxiety
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Assessment of pain severity in pediatric patients who underwent appendectomy utilizing the Ocher pain assessment scale.
Timepoint
The child's pain score will be assessed using a 0-10 numerical rating scale or a similar visual analog scale by the child, one hour post-surgery, and then at three and six hours after the initial measurement.
Method of measurement
Ocher scale

2

Description
Assessment of anxirty severity in pediatric patients who underwent appendectomy utilizing the OSBD-R scale (Observed Behavioral Distress Scale– Revise)
Timepoint
Post-operative anxiety levels are assessed by the researcher during the first hour, then three hours and six hours from the first measurement.
Method of measurement
OSBD-R scale (Observed Behavioral Distress Scale–Revise)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: After being transferred from the recovery room to the surgical ward, the patient will receive routine care. Then, using the Ochre tool, the child will be asked to rate their pain level from zero to 10 or choose a similar image. The level of anxiety will also be scored by the researcher using the OSBD-R tool. Next, the necklace containing 5 drops of the first scent (lavender essential oil made by Ellis Company with health code 36/13365) will be hung around the child's neck by the researcher to inhale the scent. The necklace is made of soft, porous yarn and mesh, which is completely hygienic and hypoallergenic, and its length can be adjusted to be at a safe and appropriate distance from the nose and mouth. The parents/carers will be instructed on how to keep the necklace on the chest and avoid moving or manipulating it. Three hours after the first measurement, the child's pain will be scored using the Ochre tool and anxiety will be scored using the OSBD-R tool. For proper efficacy and to prevent normalization of the inhaled odor, the odor is renewed and again 3 hours later (6 hours after the first measurement) pain will be scored using the Ochre tool and anxiety will be scored using the OSBD-R tool. The number of drops and the intervals of patient assessment for pain and anxiety are modeled according to previous similar studies conducted on pediatric populations.

Category

Treatment - Drugs

2

Description

Intervention group2: After being transferred from the recovery room to the surgical ward, the patient will receive routine care. Then, using the Ochre tool, the child will be asked to rate their pain level from zero to 10 or choose a similar image. The level of anxiety will also be scored by the researcher using the OSBD-R tool. Next, the necklace containing 5 drops of the second scent (Rose flower drop made by Ellis Company with health code 36/13365) will be hung around the child's neck by the researcher to inhale the scent. The necklace is made of soft, porous yarn and mesh, which is completely hygienic and hypoallergenic, and its length can be adjusted to be at a safe and appropriate distance from the nose and mouth. The parents/carers will be instructed on how to keep the necklace on the chest and avoid moving or manipulating it. Three hours after the first measurement, the child's pain will be scored using the Ochre tool and anxiety will be scored using the OSBD-R tool. For proper efficacy and to prevent normalization of the inhaled odor, the odor is renewed and again 3 hours later (6 hours after the first measurement) pain will be scored using the Ochre tool and anxiety will be scored using the OSBD-R tool. The number of drops and the intervals of patient assessment for pain and anxiety are modeled according to previous similar studies conducted on pediatric populations.

Category

Treatment - Drugs

3

Description

Control group: After being transferred from the recovery room to the surgical ward, the patient will receive routine care. Then, using the Ochre tool, the child will be asked to rate their pain level from zero to 10 or choose a similar image. The level of anxiety will also be scored by the researcher using the OSBD-R tool. Next, the necklace containing 5 drops of distilled water will be hung around the child's neck by the researcher to inhale the scent. The necklace is made of soft, porous yarn and mesh, which is completely hygienic and hypoallergenic, and its length can be adjusted to be at a safe and appropriate distance from the nose and mouth. The parents/carers will be instructed on how to keep the necklace on the chest and avoid moving or manipulating it. Three hours after the first measurement, the child's pain will be scored using the Ochre tool and anxiety will be scored using the OSBD-R tool. Three hours later (6 hours after the first measurement) pain will be scored using the Ochre tool and anxiety will be scored using the OSBD-R tool. The intervals of patient assessment for pain and anxiety are modeled according to previous similar studies conducted on pediatric populations.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Mardani Azar Children's Hospital

Full name of responsible person

Samin Mirchraghi

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Sponsors / Funding sources

1

Sponsor

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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
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Fatemeh Ghorbani

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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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