Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of Lavender and Rose Aromatherapy on Emergence Agitation in Children Following Dental Treatment with General Anesthesia, A Clinical trial

Protocol summary

Study aim
General goals: Assessment of the effect of lavender and rose aromatherapy on emergence agitation in children following dental treatment under general anesthesia

Design
Randomized parallel-arm design, double-blind, a sample size of 57 patients

Settings and conduct
The study is carried out in the operating room of the pediatric department of the Faculty of Dentistry, Tehran University of Medical Sciences. After being extubated, the child enters the recovery room, where the diffuser was previously turned on. A fixed video camera is in front of the child's bed, broadcast live on a monitor outside the recovery room. In each group, 0, 10, 15, and 30 minutes after the child is out of deep sedation, emergence delirium, and pain severity are assessed by trained personnel; with PAED (Pediatric Anesthesia Emergence Delirium Scale) and mCHEOP scale (modified children's hospital of eastern Ontario pain scale) respectively. The assessment is done outside the recovery room. Therefore this person is blinded to the aroma used. During this time, the child's nausea or vomiting and need for painkillers are also recorded. After all data collection, statistical analysis is performed to look for meaningful differences between the three groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria 1. Children between 3 to 6 years old 2. Children requiring dental treatment on deciduous teeth under general anesthesia 3. Children classified as groups 1 and 2 of the ASA (American Society of Anaesthesiologists) grading system 4. Parent or guardian's consent Exclusion criteria 1. Nasal obstruction 2. Children requiring dental extraction

Intervention groups
Intervention groups 1. Lavender group 2. Rose group 3. control group

Main outcome variables
emergence delirium; pain severity; postoperative nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230114057124N1**
Registration date: **2023-04-26, 1402/02/06**
Registration timing: **prospective**

Last update: **2023-04-26, 1402/02/06**
Update count: **0**

Registration date
2023-04-26, 1402/02/06

Registrant information

Name
Maryam Sadr Hosseini

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2228 5292

Email address
ms-sadrhosseini@student.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-30, 1402/02/10

Expected recruitment end date
2023-06-22, 1402/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Lavender and Rose Aromatherapy on Emergence Agitation in Children Following Dental Treatment with General Anesthesia, A Clinical trial

Public title

Effect of Lavender aromatherapy on emergence agitation

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Children requiring dental treatment on deciduous teeth under general anesthesia Children classified as groups 1 and 2 of the ASA grading system

Exclusion criteria:

Children requiring dental extraction Nasal obstruction

Age

From **3 years** old to **6 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **57**

Randomization (investigator's opinion)

Randomized

Randomization description

Daily, about ten children are admitted for dental procedures under general anesthesia in the Faculty of Dentistry operating room between 7:00 am and 2:00 pm. The duration of surgeries vary, and the exact time children are brought to the recovery room is unknown. When the aroma diffuser is turned on in the recovery room, the plant's aroma remains until the end of the session, and it needs to be ventilated for the next aroma in the room. Therefore, it is possible to use one aroma each day, and all the children admitted will inhale the same aroma. According to the limitations of the intervention, random allocation is done in a cluster manner. Three identical bottles, one containing lavender, one containing rose, and one containing distilled water, are prepared. These bottles are named (A, B, C). Three closed envelopes are also prepared, each with one of A, B, or C written inside. The envelopes are numbered (1, 2, 3). On the first day of the trial, 1 hour before admission of the first patient, one of the numbers 1, 2, or 3 is selected using a random number generator, and the envelope is opened. Next, the contents of the corresponding bottle are poured into the diffuser. On the second day, using a random number generator, one of the numbers is selected, and the envelope is opened. On the third day, the remaining contents of the bottle are poured into the diffuser. On the fourth day, one of the three envelopes is chosen again. This process continues until the participants of all three groups reach 19 people.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participant: The children's consciousness is altered after general anesthesia; therefore, they are considered blind. Researcher: Essential oils containers are identical and numbered. The researcher is unaware of the aroma assigned to each group. Outcome evaluator: To blind this person to the diffused aroma, the child's condition is filmed in the recovery room. The evaluator evaluates the child without being aware of the diffused aroma. Data Analyzer: Evaluations are recorded by bottle number. The analyzer is aware of the people in a group but unaware of the aroma assigned to each group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Dentistry-Tehran University of Medical Sciences

Street address

Tehran university of medical sciences dental school, North Karegar St.,Tehran-Iran

City

Tehran

Province

Tehran

Postal code

1439955991

Approval date

2022-12-20, 1401/09/29

Ethics committee reference number

IR.TUMS.DENTISTRY.REC.1401.118

Health conditions studied

1

Description of health condition studied

Postoperative emergence delirium

ICD-10 code

F05.8

ICD-10 code description

An etiologically nonspecific organic cerebral syndrome characterized by concurrent disturbances of

consciousness and attention, perception, thinking, memory, psychomotor behaviour, emotion, and the sleep-wake schedule. The duration is variable and the deg

Primary outcomes

1

Description
The PAED score in the recovery room
Timepoint
0, 10, 15 and 30 minutes after coming out of deep sedation
Method of measurement
PAED (pediatric anesthesia emergence delirium) scale

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: 30 minutes before starting the surgery, in the lavender group (A), 15 drops of lavender essential oil (Tabib Daro, Iran) is poured into 350 ml of city water and diffused by an aroma diffuser (Aroma Diffuser, Muji, Japan). The diffuser is placed in the recovery room where the child is transferred immediately after extubation. The diffuser remains on until the last child is discharged from the recovery ward. In the lavender and rose groups, the diffuser is filled as needed to establish the ratio of water and essential oil.
Category
Prevention

2

Description
Intervention group: In this group, 10 drops of rose essential oil (Tabib Daro, Iran) is poured into 350 ml of city water and diffused by a diffuser. Details are similar to the lavender group.
Category
Prevention

3

Description
Control group: In this group, the diffuser device containing 350 ml of city water is placed in the recovery without any additives. Details are similar to intervention groups.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Pedodontics department, Tehran university of medical sciences dental school
Full name of responsible person
Maryam sadat Sadrhosseini
Street address
Tehran university of medical sciences dental school, North Karegar St.,Tehran-Iran
City
Tehran
Province
Tehran
Postal code
1439955991
Phone
+98 21 8801 5801
Fax
+98 21 8801 5800
Email
sch-dentistry@tums.ac.ir
Web page address
http://dentistry.tums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. akbar fotoohi
Street address
6th floor, Central Building of Tehran University of Medical Sciences: No. 226, Qods St., Keshavarz Blvd., Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3658
Email
vcr@sina.tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Maryam Sadr Hosseini

Position

Dental Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street address

North Karegar St,Tehran-Iran

City

Tehran

Province

Tehran

Postal code

1439955991

Phone

+98 21 8801 5801

Fax

Email

ms-sadrhosseini@student.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Saeede Mokhtari

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Tehran university of medical sciences dental school, North Karegar St.,Tehran-Iran

City

Tehran

Province

Tehran

Postal code

1439955991

Phone

+98 21 8801 5801

Email

smokhtari@tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Maryam Sadr Hosseini

Position

Dental Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street address

No. 10, Shamira St., Soudeh St., Yaser St., Niavaran

City

Tehran

Province

Tehran

Postal code

1977666314

Phone

+98 21 2228 5292

Fax

Email

ms-sadrhosseini@student.tums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available