Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of rosa and peppermint scents on postoperative pain and anxiety in 6-12 years children with abdominal surgery

Protocol summary

Study aim

Determining the effect of aromatherapy with rose water and peppermint on pain and anxiety caused by abdominal surgery in children aged 6 to 12 years.

Design

The clinical trial has fragrance groups with rose water, peppermint and control group. The sample size was estimated to be 32 people in each group. Taking into account the 10% loss of the studied samples, the final volume in each group will be 36 people. Allocation of samples in groups is done using random block method. It is used in order to equalize the distribution of confounding variables of gender and level of anxiety before the intervention.

Settings and conduct

Ali Asghar Children's Center in Tehran, data collection tools in this research include the demographic information collection form, FLACC pain behavioral response checklist, and Hamilton's anxiety questionnaire. The children will be placed in one of the groups with the scent of rose water, scent with peppermint and the control group. Allocation of the samples in the groups is done using random block method. In the intervention groups, 2 drops of rose oil or peppermint essence will be poured on the pad soaked in normal saline and will be attached to the collar of the child's clothes for half an hour immediately after removing the pad. , the child's pain and anxiety will be measured, in the control group, a pad soaked in normal saline without fragrance will be used.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The child is 12-6 years old; performing elective abdominal surgery

Intervention groups

Rose scent, peppermint scent and control group

Main outcome variables

Heart rate, breathing and blood oxygen saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230409057861N1**
Registration date: **2023-11-08, 1402/08/17**
Registration timing: **prospective**

Last update: **2023-11-08, 1402/08/17**
Update count: **0**

Registration date

2023-11-08, 1402/08/17

Registrant information

Name

Zahra Nadri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 5828 2618

Email address

pr.lums@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-05, 1402/12/15

Expected recruitment end date

2024-07-05, 1403/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of rosa and peppermint scents on postoperative pain and anxiety in 6-12 years children with abdominal surgery

Public title

Comparison of rosa and peppermint scents on postoperative pain and anxiety in children with abdominal surgery

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Having both parents Children should be 6 to 12 years old The child should be awake before the surgery Always accompany the child and only the mother Verbal consent of the child to participate in the stud Ability of child and mother to communicate verbally Performing elective abdominal surgery in children Presence of the child and mother at least 12 hours before and 18 hours after the operation in the ward

Exclusion criteria:

Prolonging surgery in the operating room Having complications during surgery and complications of anesthesia (severe hypothermia) The occurrence of unwanted complications after surgery such as bleeding, opening of the surgical site, etc. Need for ICU after surgery Child's and mother's unwillingness to continue the research Moving the child to another department/hospital Discharge of children from the hospital with personal consent the impossibility of the parent being with the child during the entire period of hospitalization for any reason (illness, personal problems, etc Disruption in completing the anxiety questionnaire by the mother Occurrence of symptoms of allergy to scents in the child or mother during the study Patients with acute problems and undergoing emergency surgeries The child has multiple surgical incisions Performing major abdominal surgeries (volvulus, laparotomy obstruction) and multiple incisions History of surgery or hospitalization in the child Physical and metabolic diseases such as diabetes and phenylketonuria in children History of allergic rhinitis in child and mother History of respiratory, skin and dermatitis sensitivity in child and mother The presence of chronic pain in children Taking painkillers or sedatives during 24 hours before abdominal surgery by the child Taking nerve medication or suffering from nerve diseases such as anxiety and depression, hyperactivity and autism Use of hypnotics, sedatives or benzodiazepines by the child within a week before the start of the intervention. Use of systemic painkillers such as ibuprofen and acetaminophen before surgery in children Use of complementary medicine methods (aromatherapy, etc.) for the child and parents for a week before the intervention. A child suffering from mental retardation Obvious cognitive, psychological or physical problems in parents and children

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Allocation of samples in groups is done using random block method. In order to equalize the distribution of gender confounding variables and the level of anxiety before the intervention, first classes based on these variables as described by girl/boy and mild (≥17)/moderate (18-24)/severe (25-30)/very severe anxiety (<30) are created and then they are balanced in the studied groups by random block method

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is one-sided blind and the statistical consultant is blind. After collecting the data without identifying the intervention and control groups, descriptive statistics are used to describe the data, calculating central and dispersion indices for quantitative variables and frequency and percentage for qualitative variables.

Placebo

Used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Lorestan University of Medical Sciences

Street address

Moalem ave

City

Khoram Abad

Province

Lorestan

Postal code

6813833946

Approval date

2023-02-04, 1401/11/15

Ethics committee reference number

IR.LUMS.REC.1401.302

Health conditions studied

1

Description of health condition studied
Abdominal surgery
ICD-10 code
Z40.8
ICD-10 code description
Encounter for other prophylactic surgery

Primary outcomes

1

Description
Percentage of children candidates for abdominal surgery
Timepoint
Hospitalization time in the ward and before aromatherapy, immediately after the operation and at half an hour, 3, 6, 9, 12 and 16 hours after the operation
Method of measurement
Data collection tools in this research include the demographic information collection form, FLACC pain behavioral reaction checklist, and Hamilton's anxiety questionnaire.

Secondary outcomes

1

Description
Blood oxygen saturation percentage
Timepoint
at the time of entering the ward and before aromatherapy, and at half, 3, 6, 9, 12 and 16 hours after the operation
Method of measurement
Pulse oximetry device

Intervention groups

1

Description
Intervention group: In the intervention groups, 2 drops of rose essential oil or peppermint will be poured on a pad soaked in normal saline and will be attached to the collar of the child's clothes for half an hour. Immediately after removing the pad, the child's pain and anxiety will be measured. In the control group, A pad soaked in unscented normal saline will be used. The anxiety of the units studied by the researcher and assistant researchers one hour after the child's hospitalization before receiving the scent and 8 hours after hospitalization, 9, 12 and 16 hours after the operation and receiving the scent half an hour before the above hours with the Hamilton tool through an interview with the mother by the researchers will be measured. Also, children's pain will be measured using Flak tool upon entering from the operating room to the ward before giving the aroma at half, three, six, nine, twelve and sixteen hours after the operation and receiving the aroma for half an hour by the researcher and assistant researchers.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ali Asghar Childrens Hospital
Full name of responsible person
Fatemeh ghasemi
Street address
Zafar Ave, Modares Highway
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Tehran
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1411863887
Phone
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Email
aliasghar@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Fatemeh ghasemi
Street address
Lorestan univercity of medica scieces, anvoshirvan rezaei square, moalem ave
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6895113132
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Email
ghasemi2211156@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Khoram-Abad University of Medical Sciences
Proportion provided by this source
50
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
Khoram-Abad University of Medical Sciences
Full name of responsible person
Zahra nadri
Position
Nurse
Latest degree
Master
Other areas of specialty/work
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Person responsible for updating data

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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
The result was unclear due to the reason
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