Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Comparative assessment of the effect of aromatherapy with Citrus Aurantium and Vanilla essence on pain intensity, blood pressure and perceived postoperative stress in adolescents undergoing appendectomy

Protocol summary

Study aim
Comparison the effect of aromatherapy with Citrus Aurantium and vanilla essence on pain intensity, blood pressure and perceived stress after the operation of adolescents undergoing appendectomy in the pediatrics surgery department of Namazi Hospital in Shiraz 2023.

Design
Clinical trial with control group, with parallel groups, one-sided blind, randomized, phase 0 on 75 patients, permutation block method is used for randomization.

Settings and conduct
This study is conducted at Namazi Hospital in Shiraz and on three groups of teenagers randomly after appendectomy. The study is single-blind. The two intervention groups receive spring orange and vanilla scents separately, and paraffin is used as a placebo in the control group.

Participants/Inclusion and exclusion criteria
inclusion criteria: for participants: age between 11 _18 years, absence of cognitive and mental problems, no history of sensitivity to scents or herbal substances, hospitalization due to appendectomy. exclusion criteria: unwillingness to continue participating in the study, death of the patient, incomplete completion of questionnaires, smell problems, disturbance in the patient's level of consciousness, need for mechanical ventilation

Intervention groups
In the Citrus Aurantium group, extract with a concentration of 0.1% in 10 cc, in the vanilla group with a concentration of 10 mg in 10 cc, and in the control group, paraffin is used as a placebo. 2 ml of the extract is poured on the eye pad and at the time of entering the ward, 3 and 6 hours after the operation, it is placed at a distance of 30 cm from the child's nose and the child takes three deep breaths. The patient's blood pressure is measured and the McGill pain and depression, anxiety, and stress questionnaires are completed.

Main outcome variables
Intensity of pain, perceived stress and blood pressure.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231211060336N1**
Registration date: **2023-12-25, 1402/10/04**
Registration timing: **prospective**

Last update: **2023-12-25, 1402/10/04**
Update count: **0**

Registration date
2023-12-25, 1402/10/04

Registrant information

Name
Parisa Haji mohammadi ghahnavieh

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
2024-01-21, 1402/11/01

Expected recruitment end date
2024-03-20, 1403/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative assessment of the effect of aromatherapy with Citrus Aurantium and Vanilla essence on pain intensity, blood pressure and perceived postoperative stress in adolescents undergoing appendectomy

Public title
A comparative assessment of the effect of aromatherapy with Citrus Aurantium and vanilla essence on pain intensity, blood pressure and perceived stress in adolescents undergoing appendectomy.
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 11 and 18 years Absence of cognitive and mental problems based on the opinion of a specialist doctor No history of allergy to scents or herbal substances based on parents' statements Hospitalization due to appendectomy surgery
Exclusion criteria:
Failure to continue participating in the study Death of the patient After the operation for any reason Incomplete completion of questionnaires Adolescent patients with olfactory problems Changes in the patient's level of consciousness The need to use mechanical ventilation devices for the patient
Age
From **11 years** old to **18 years** old
Gender
Both

Phase
0
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **75**
Randomization (investigator's opinion)
Randomized
Randomization description
Samples are selected from eligible individuals based on entry criteria; Then they are divided into three groups using the permuted block method; In order to balance and divisible the number of blocks and each block is a multiple of three, a sample size of 81 people is considered and finally people will be allocated in 9 blocks of 9 blocks. 0001: A 0003: A 0005: B 0007: A 0009: C 0002: C 0004: B 0006: B 0008: C _____ 0010: A 0012: B 0014: B 0016: A 0018: C 0011: B 0013: C 0015: C 0017: A _____ 0019: B 0021: A 0023: C 0025: A 0027: B 0020: C 0022: C 0024: A 0026: B _____ 0028: C 0030: B 0032: B 0034: C 0036: A 0029: A 0031: A 0033: C 0035: B _____ 0037: A 0039: B 0041: C 0043: B 0045: A 0038: C 0040: B 0042: A 0044: C _____ 0046: B 0048: A 0050: B 0052: B 0054: A 0047: C 0049: C 0051: A 0053: C _____ 0055: B 0057: C 0059: A 0061: C 0063: B 0056: B 0058: A 0060: A 0062: C _____ 0064: A 0066: B 0068: C 0070: C 0072: B 0065: A 0067: B 0069: A 0071: C _____ 0073: C 0075: A 0077: B 0079: B 0081: A 0074: A 0076: C 0078: B 0080: C _____ 0082: A 0084: A 0086: B 0088: C 0090: C 0083: B 0085: A 0087: C 0089: B _____
Blinding (investigator's opinion)
Single blinded
Blinding description
Only the participants did not know which group they were placed in and whether they were prescribed aromatherapy or a placebo.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences
Street address
Shiraz University of Medical Sciences, Zand Blvd., Shiraz, Iran
City
Shiraz
Province
Fars
Postal code
71348-14336
Approval date
2023-11-11, 1402/08/20
Ethics committee reference number
IR.SUMS.NUMIMG.REC.1402.104

Health conditions studied

1

Description of health condition studied
Intensity of pain, blood pressure and perceived stress after the operation of adolescents undergoing appendectomy surgery
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pain intensity
Timepoint
Pain measurement is performed when the patient enters the surgery department (before the intervention),1, 3 and 6 hours after the first intervention.
Method of measurement
McGill Pain Assessment Questionnaire

2

Description
Blood pressure
Timepoint
Blood pressure is measured when the patient enters the surgery ward (before the intervention),1, 3 and 6 hours after the first intervention.
Method of measurement
Mercury sphygmomanometer

3

Description
Perceived stress
Timepoint
Perceived stress is measured using the depression, anxiety, and stress scale when the patient enters the surgery ward (before the intervention) and 1, 3, 6 hours after the first intervention.
Method of measurement
Depression, anxiety, stress scale(DASS-21)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1:A group of 25 people is selected to conduct a trial with Citrous Aurantium essential oil by random sampling method (permutation block). Spring orange extract with a concentration of 0.1% in 10 cc (preparation and standardization of spring orange extract, by the traditional medicine pharmacy team of Shiraz University of Medical Sciences Faculty of Pharmacy and with the approval of one of the faculty members of the Faculty of Pharmacy, affiliated to Shiraz University of Medical Sciences.) in the amount of 2 ml using a dropper on a standard and clean eye pad and the pad is placed inside a suitable can and at the time of entering the ward (first pain measurement), 3 and 6 hours after the operation, in A distance of 30 cm from the child's nose is placed and the child is asked to take three deep breaths. Repetition of aromatherapy every 3 hours is appropriate to prevent normalization of the smell inhaled from the scent and to renew its smell in order to be effective. All pads are kept in a closed box between times of use; It should be noted that the pads used are only for one patient. After the patient enters the pediatric surgery department, the patient's blood pressure will be measured, and then the McGill pain questionnaire and the depression, anxiety, and stress questionnaire will be completed, and after that, the aromatherapy intervention will be performed for the first time; One hour after the first intervention, blood pressure will be measured for the second time and questionnaires will be completed; Also, three hours after the operation, the intervention is performed again, and questionnaires are completed and blood pressure measurement is done after one hour. After six hours of surgery, the intervention will be done for the last time, and one hour after that, questionnaires will be completed and the patient's blood pressure will be measured and recorded. Medical and nursing care will be performed according to routine. Data are collected and analyzed using SPSS software and statistical tests.
Category
Treatment - Other

2

Description
Intervention group2: A group of 25 people is selected to conduct a trial with Vanilla essence using a random sampling method (permutation block). Vanilla extract with a concentration of 10 mg in 10 cc (preparation and standardization of vanilla extract by the traditional medicine pharmacy team of the Faculty of Pharmacy of the University of Medical Sciences Shiraz and with the approval of one of the faculty members of the Faculty of Pharmacy, affiliated to Shiraz University of Medical Sciences) in the amount of 2 ml was poured on a clean standard eye pad using a dropper and the pad was placed inside a suitable can. and at the time of entering the ward (first pain measurement), 3 and 6 hours after the operation, it is placed at a distance of 30 cm from the child's nose and the child is asked to take three deep breaths. Repetition of aromatherapy every 3 hours is appropriate to prevent normalization of the smell inhaled from the scent and to renew its smell in order to be effective. All pads are kept in a closed box between times of use; It should be noted that the pads used are only for one patient. After the patient enters the pediatric surgery department, the patient's blood pressure will be measured, and then the McGill pain questionnaire and the depression, anxiety, and stress questionnaire will be completed, and after that, the aromatherapy intervention will be performed for the first time; One hour after the first intervention, blood pressure will be measured for the second time and questionnaires will be completed; Also, three hours after the operation, the intervention is performed again, and questionnaires are completed and blood pressure measurement is done after one hour. After six hours of surgery, the intervention will be done for the last time, and one hour after that, questionnaires will be completed and the patient's blood pressure will be measured and recorded. Medical and nursing care will be performed according to routine. Data are collected and analyzed

using SPSS software and statistical tests.

Category

Treatment - Other

3

Description

Control group: Control group: In the control group, Paraffin is used as a placebo. A group of 25 people is selected to conduct a trial with paraffin as a placebo by random sampling method (permutation block). Preparation and standardization of paraffin by the traditional medicine pharmacy team of Shiraz University of Medical Sciences and with the approval of one of the professors. Scientific Faculty of Pharmacy, affiliated to Shiraz University of Medical Sciences, 2 ml is poured on a standard and clean eye pad using a dropper, and the pad is placed inside a suitable can and at the time of entering the department The first pain measurement), 3 and 6 hours after the operation, is placed at a distance of 30 cm from the child's nose and the child is asked to take three deep breaths. Repetition of aromatherapy every 3 hours. It should be noted that the pads used are only for one patient. After the patient enters the pediatric surgery department, the patient's blood pressure will be measured, and then the McGill pain questionnaire and the depression, anxiety, and stress questionnaire will be completed, and after that, the aromatherapy intervention will be performed for the first time; One hour after the first intervention, blood pressure will be measured for the second time and questionnaires will be completed; Also, three hours after the operation, the intervention is performed again, and questionnaires are completed and blood pressure measurement is done after one hour. After six hours of surgery, the intervention will be done for the last time, and one hour after that, questionnaires will be completed and the patient's blood pressure will be measured and recorded. Medical and nursing care will be performed according to routine. Data are collected and analyzed using SPSS software and statistical tests.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi hospital

Full name of responsible person

Parisa hajimohammadi ghahnavieh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Parisa Haji mohammadi ghahnavieh

Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Title and more details about the data/document
Only part of the data, such as information related to the main outcomes, which can be shared after de-identifying individuals, will be shared. Data related to study outcomes, such as the effects of extracts on pain intensity, blood pressure, and perceived stress after Appendectomy surgery in adolescents hospitalized in the pediatric surgery department.
When the data will become available and for how long
The access period starts 6 months after the results are published.
To whom data/document is available
Researchers working in universities
Under which criteria data/document could be used
Requesting the use of documents is unimpeded for researchers.
From where data/document is obtainable
To receive documents, use the following email. Parisahajimohammad71@yahoo.com
What processes are involved for a request to access data/document
After the university researchers send the request to the mentioned email address, a brief description of the applicant should also be sent; after reviewing the application, if there are no problems, the documents will be sent.
Comments
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