# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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

**Full name of responsible person**

Mohammad Hashem Hashempour

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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 updating data

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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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