Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of aromatherapy inhalation with geranium essence on physiological Parameter and post operative complications of appendectomy

Protocol summary

Study aim
Determination the Effect of Inhalation aromatherapy with Essential Oil on Physiological Indices and Postoperative Complications of Appendectomy

Design
Clinical trials with placebo and control group,parallel, double blind, randomized clinical trials

Settings and conduct
research is conducted in Neyshabour University of Medical Sciences.In the test group, three drops of 1% aromatic geranium essential oil are manufactured by Barij Essence Company on a pad and patients are asked to inhale it for 5 minutes at a distance of 10 cm from the face at specified intervals and indicators of pain intensity, nausea, vomiting and physiological symptoms.In the placebo group, three drops of essential oil of sweet almonds, making the barium essential oil on a pad, and the same as the test group, are subjected to a medical treatment.There is no intervention in the control group and patients are treated with routine care. Examples and researcher assistance that measures the variables are unaware of the nature of the groups

Participants/Inclusion and exclusion criteria
Satisfied to participate in the study;Appendectomy is undergoing open procedure;Under general anesthesia;After surgery they are alert;The age of patients is between 15 and 45 years;Do not have drug addiction;Do not have a history of allergy ;There are no underlying illnesses;The duration of surgery should not exceed one hour;Do not have NGT The occurrence of any unexpected complications during an intervention;Deny the patient from participating in the intervention

Intervention groups
Patients will assess the effect of aromatherapy with geranium essence.Patients will test the effect of the sweet almond essence on them.The control group There is no intervention on them and they are treated with routine treatments.

Main outcome variables
Physiological indices, pain, nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170131032329N2**
Registration date: **2018-09-26, 1397/07/04**
Registration timing: **registered_while_recruiting**

Last update: **2018-09-26, 1397/07/04**
Update count: **0**

Registration date
2018-09-26, 1397/07/04

Registrant information

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Mahnaz Abavisani

Name of organization / entity
Gonabadl University Medical of Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-09-23, 1397/07/01

Expected recruitment end date
2018-11-22, 1397/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of aromatherapy inhalation with geranium essence on physiological Parameter and post operative complications of appendectomy

Public title

The effect of aromatherapy inhalation with geranium essence on physiological Parameter and post operative complications of appendectomy

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Satisfied to participate in the study Appendectomy is undergoing open procedure Under general anesthesia After surgery, they are alert and have no known cognitive or psychological disorder Patients with anesthesia risks 1 and 2 The age of patients is between 15 and 45 years Do not consume drugs and not addicts Do not have a history of allergies and allergies There are no known underlying diseases Duration of surgery should not exceed one hour Do not have NG tube

Exclusion criteria:

The occurrence of any unexpected complications during an intervention that prevents further work with the patient, such as a severe reduce in blood pressure and other complications that may interfere with the patient's experience Deny the patient from participating in the intervention

Age

From **15 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to randomly assign individuals to the three groups and guaranteeing the balance of the number of people in groups, a random block method will be used.Sampling is done in several steps.In this study, the block size will be considered as six.Consequently, using randomized blocking, the participants randomly divided into three groups of aromatic herbal fragrances, aromatic herbs with a sweet almond and control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Research units, as well as researcher's help, which measure pain intensity, are unaware of the nature of the groups

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Neyshabur University of Medical Sciences

Street address

NO 489, North Asadabadi 17, North Arg Ave

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Province

Razavi Khorasan

Postal code

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Approval date

2018-09-08, 1397/06/17

Ethics committee reference number

IR.NUMS.REC.1397.18

Health conditions studied

1

Description of health condition studied

appendicitis

ICD-10 code

(K35-K38)

ICD-10 code description

(K00-K93)

Primary outcomes

1

Description

Pain score according to VAS scale

Timepoint

Measuring the intensity of pain when entering the operating room, when the patient enters recovery in the first time that the patient is able to respond, when leaving the recovery, 4 hours after surgery

Method of measurement

VAS Scale

2

Description

Vomiting Nausea Score based on the visual scale of the

severity of nausea

Timepoint

Before entering the operating room, after entering the recovery, immediately after the second intervention, before leaving the recovery, 4 hours after the operation

Method of measurement

the visual scale of the severity of nausea

3

Description

Physiological Indices

Timepoint

Before entering the operating room, before induction of anesthesia, before the operation, after the completion of the operation, after entering the recovery, immediately after the second intervention, before leaving the recovery

Method of measurement

Using finger pulse oximeter and monitoring device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the aromatherapy group with geranium essence three grams of aromatic geranium essential oil of 1% maked by Barij Essence company are poured onto a pad and patients are asked to inhale it for 5 minutes at a distance of 10 cm from the face. At this time, the patient is prepared for anesthesia. Before induction of anesthesia, physiological symptoms are recorded before the operation is completed before the operation begins. When the patient enters a recovery, the patient is first responded with pain, nausea, vomiting and physiological symptoms. The patient is subjected to aromatherapy with geranium essence for a second time for 5 minutes, Immediately after the intervention and When the patient leaves the recovery (30 minutes after the patient's recovery) and 4 hours after the operation. Severity of pain, nausea, vomiting and physiological symptoms are recorded.

Category

Treatment - Other

2

Description

second intervention group: In the placebo group, during the delivery of the patient from the surgery ward to the operating room, a check list for pain intensity assessment according to the VAS scale, the visual scale of nausea and physiological indicators for the first time are completed and recorded.Patients with sweet almonds are inhaled.In the aromatherapy group with sweet almonds three drops of sweet almond essnce are made by Barij Essence company pured on a pad, and patients are asked to inhale it for 5 minutes at a distance of 10 cm from the face.At this time, the patient is prepared for anesthesia.Before induction of anesthesia, physiological symptoms are recorded before the operation is completed before the operation begins. When the patient enters recovery, the pain, nausea, vomiting and physiological symptoms are recorded at the first time that the patient is able to respond.The patient is subjected to a sweet almond oil for a second time for 5 minutes.Then immediately after the intervention and when the patient leaves the recovery(30 minutes after the patient enters the recovery)And 4 hours after the operation, the severity of pain, nausea, vomiting and physiological symptoms are recorded.

Category

Other

3

Description

Control group: In the control group, no intervention is performed and only the severity of the pain and vomiting and physiological indices in the mentioned stages are recorded and recorded, and patients are only treated with routine care.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

22 Bahman Hospital

Full name of responsible person

Mahnaz Abavisani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Web page address
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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
Neyshabour 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

2

Sponsor
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Web page address
https://www.nums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Neyshabour 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
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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
No more 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
Undecided - It is not yet known if there will be a plan to make this available