Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Compare the efficacy of aromatherapy with essential oils of lavender and Citrus aurantium on anxiety before laparoscopic surgery In two intervention group and a control group.

Protocol summary

Summary

The aim of this study is to compare the effect of two methods of aromatherapy; Lavender and citrus aurantium essence; on severity of anxiety before undergoing a Laparoscopic cholecystectomy surgery, in which patients, based on inclusion and exclusion criteria, will be divided in three groups; intervention with Lavender essence, citrus aurantium essence, and control. This study is a single-blind clinical trial that will be conducted on 90 patients. Before intervention, patients must fill out Spiel-Berger anxiety-measuring questionnaire to record basic anxiety. the patients who get 20 (minimum mark) will be entered the study. Then in intervention group, we pour two drops of Lavender essence and citrus aurantium essence by a dropper on a piece of tissue and let the patients to smell it for 20 minutes. After that by Spiel-Berger questionnaire, patients' anxiety will be measured, finally, the effects of the essences will be studied.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017031433083N1**
Registration date: **2017-06-26, 1396/04/05**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-06-26, 1396/04/05

Registrant information

Name

Abed Ebrahimi

Name of organization / entity

Fatemeh(P.U.H) School of Nursing & Midwifery Shiraz -Iran

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2017-04-04, 1396/01/15

Expected recruitment end date

2017-05-19, 1396/02/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the efficacy of aromatherapy with essential oils of lavender and Citrus aurantium on anxiety before laparoscopic surgery In two intervention group and a control group.

Public title

Comparison of the effect of aromatherapy with essential oils of lavender and Citrus aurantium on anxiety.

Purpose

Prevention

Inclusion/Exclusion criteria

Admittance and exit standards Study entrance standards: male and female 40 years and older patients; patients who are getting (Cholecystectomy) surgery with

Laparoscopy method; patients must be conscious; they have not taken sedatives; not used anti-anxiety drugs and herbal medicines; non addicted to drugs (according to the patients' saying); non-working patient in therapeutic and hygienic jobs; not having any vision, hearing, and olfaction problems according to the patients' saying; not having severe difficulties; getting a score higher than 20 (light anxiety) after answering to Spill Berger questionnaire; patients having light or normal anxiety; able to think and speak in Persian Language. Study exit standards: severe pain while completing questionnaire; willing to exit in any level of intervention; patients with having severe anxiety; patients who are getting emergency surgery of Cholecystectomy.

Age
From **40 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Stratified random sampling method hospital then patients are randomly divided into three groups block.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Shiraz- zand Street

City
Shiraz

Postal code

Approval date
2017-03-12, 1395/12/22

Ethics committee reference number
IR.SUMS.REC.1395.196

Health conditions studied

1

Description of health condition studied
Anxiety

ICD-10 code
F41.2

ICD-10 code description
Mixed anxiety and depressive disorder

Primary outcomes

1

Description
Anxiety

Timepoint
Before the intervention and after the intervention in the preoperative

Method of measurement
Questionnaire Spillberger

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention group 1: 2 drops of Lavandula oil 100% will Poured on the cloth and would be inhaled in 20 minutes by the patient.

Category
Treatment - Other

2

Description
In the intervention group 2: 2 drops of Citrus aurantium oil 100% will Poured on the cloth and would be inhaled in 20 minutes by the patient.

Category
Treatment - Other

3

Description
In the control group: 2 drops of sweet almond oil will Poured on the cloth and would be inhaled in 20 minutes by the patient.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Nemazi Hospital
Full name of responsible person
Jamshid Eslami
Street address
Shiraz - Namaz Square
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research Shiraz University of Medical Sciences
Full name of responsible person
Dr. Seid Basir Hashemi
Street 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
Vice chancellor for research Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty