

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparing the Effect of aromatherapy with Geranium Essence and Lemon on situational anxiety and physiologic indexes of patients after coronary angioplasty

Protocol summary

Study aim

Comparison of effect of aromatherapy with geranium and lemon essential oil on situational anxiety and physiological parameters of patients after coronary angioplasty

Design

This is a clinical trial study with control group, with parallel groups, double-blind, randomized, phase 3 on 150 patients. Patients are randomly assigned to three groups (1, 2, and 3) by a random allocation concealment method without any comments. To perform the intervention, researcher pours three drops of geranium essential oil, three drops of lemon essential oil and three drops of placebo or sweet almond oil on a cloth and attaches it to the shirts of the subjects in the desired groups to perfume patients for 20 minutes. Expose to inhalation. After 20 minutes, situational anxiety questionnaire is completed again by samples and physiological indicators are measured.

Settings and conduct

This research will be performed in Shahid Chamran Hospital in Isfahan, is a double-blind study in which essential oil and control bottles are covered with black tape, the type of which is unknown to health care providers and patients.

Participants/Inclusion and exclusion criteria

The study population includes all patients who undergo coronary angioplasty in Shahid Chamran Hospital in Isfahan. Inclusion criteria: Willingness to participate in study, Ability and willingness to complete the questionnaire non-Inclusion criteria: history of allergies, use of painkillers or anti-anxiety drugs before the study, Existence of hearing, olfactory and mental problems, Existence of acute and chronic mental illnesses

Intervention groups

We have 3 groups: geranium essential oil (group 1), lemon essential oil (group 2) and control group (sweet

almond oil - group 3). The essential oil and control bottles will be covered with black tape and its type is unknown to healthcare provider.

Main outcome variables

Situational anxiety, physiological parameters

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201209049662N1**

Registration date: **2020-12-25, 1399/10/05**

Registration timing: **retrospective**

Last update: **2020-12-25, 1399/10/05**

Update count: **0**

Registration date

2020-12-25, 1399/10/05

Registrant information

Name

Maryam Asadi Mobarakeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-21, 1399/04/31

Expected recruitment end date

2020-10-21, 1399/07/30

Actual recruitment start date

2020-07-21, 1399/04/31

Actual recruitment end date

2020-10-21, 1399/07/30

Trial completion date

2020-10-22, 1399/08/01

Scientific title

Comparing the Effect of aromatherapy with Geranium Essence and Lemon on situational anxiety and physiologic indexes of patients after coronary angioplasty

Public title

Effect of aromatherapy situational anxiety and physiologic indexes of patients after coronary angioplasty

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Willingness to participate in the study Ability and willingness to complete the questionnaire Have not undergone other invasive procedures such as esophageal echocardiography before angioplasty. Everyone is fully conscious and not in a critical condition

Exclusion criteria:

Use painkillers or anti-anxiety medications before the study Existence of hearing, olfactory and mental problems Existence of acute and chronic mental illnesses History of allergy to the geranium plant or extract and lemon fruit or extract Postoperative complications (severe pain, active bleeding or infection)

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample sizeTarget sample size: **150**Actual sample size reached: **150****Randomization (investigator's opinion)**

Randomized

Randomization description

In this study, no patient will be aware of their group and a random sequence will be performed, and the method of using randomly coded boxes will be used. In this method, a number of boxes selected by the researcher as the first group and the same number of boxes for the next groups are considered; Then, by merging the boxes together, a box is taken out and its allocation is recorded, and that box is returned to the other boxes after being taken out. The boxes are then reassembled and another box is removed. This process continues until a random sequence according to the sample size is reached. Thus, patients will be divided into three groups: geranium essential oil (group 1), lemon essential oil

(group 2) and control group (sweet almond oil - group 3).

Blinding (investigator's opinion)

Double blinded

Blinding description

Essential oil and control bottles will be covered with black tape and its type is unknown to healthcare providers and patients.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Islamic Azad University - Isfahan (Khorasgan) Branch

Street address

University Blvd, Arqavanieh, East Jey street

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Province

Isfahan

Postal code

8155139998

Approval date

2020-08-18, 1399/05/28

Ethics committee reference number

IR.IAU.KHUISF.REC.1399.132

Health conditions studied**1****Description of health condition studied**

Coronary angioplasty

ICD-10 code

Z98.61

ICD-10 code description

Coronary angioplasty status

Primary outcomes**1****Description**

Situational Anxiety

Timepoint

Before and 20 minutes after the intervention

Method of measurement

Spielberger Standard Situational Anxiety Questionnaire

2

Description

Physiological indicators

Timepoint

Before and 20 minutes after the intervention

Method of measurement

Checklist of physiological parameters of patients including systolic and diastolic blood pressure, respiratory rate, pulse rate and arterial oxygen saturation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: Geranium Essence. The geranium essential oil used in this study was prepared by Tabib Daroo Company and according to the essential oil analysis sheet prepared by Tabib Daroo Company, this essential oil contains alphaspinene (1.35%), citronellol (37.53%), geraniol (7.2%). And citronel formate (10.03%). To perform the intervention, the researcher pours three drops of geranium essential oil on a cloth and attaches it to the shirts of the subjects in the target groups, so that patients can inhale the perfume for 20 minutes. After 20 minutes, the situational anxiety questionnaire is completed again by the samples and physiological parameters are measured.

Category

Treatment - Drugs

2

Description

Intervention group2: Lemon Essence. The essential oil of lemon used in this study was prepared by Tabib Daroo Company and according to the essential oil analysis sheet prepared by Tabib Daroo Company, this essential oil contains limonene (51.75%), betapinene (6.83%), terpinoline (5.16%). And alphaspinene (2.45%). To perform the intervention, the researcher pours three drops of lemon essential oil on a cloth and attaches it to the shirts of the subjects in the target groups, so that patients can inhale the perfume for 20 minutes. After 20 minutes, the situational anxiety questionnaire is completed again by the samples and physiological parameters are measured.

Category

Treatment - Drugs

3

Description

Control group: Sweet almond oil. To perform the intervention, the researcher pours three drops of sweet almond oil on a cloth and attaches it to the shirts of the subjects in the target groups, so that patients can inhale

the perfume for 20 minutes. After 20 minutes, the situational anxiety questionnaire is completed again by the samples and the physiological parameters are measured. The control group did not receive any intervention and is cared for according to the usual care of the ward.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Chamran Heart Educational, Therapeutic and Research Center

Full name of responsible person

Gholamreza Massoumi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Islamic Azad University

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

Isfahan

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Person responsible for updating data**Person responsible for general inquiries****Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Maryam Asadi Mobarakeh

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Other areas of specialty/work

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City

Isfahan

Province**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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