# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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 size**
Target 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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**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 alphapinene (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 alphapinene (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
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## Sponsors / Funding sources

**1**

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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

## Person responsible for general inquiries

**Contact**
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## Person responsible for updating data

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## 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