

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of aromatherapy with lemon balm versus placebo (sesame oil) on anxiety of patients with heart disease hospitalized in intensive care units: a single blind randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of aromatherapy with lemon balm versus placebo (sesame oil) on anxiety of patients with heart disease hospitalized in intensive care units. **Design:** A single blind randomized clinical trial. **Setting and conduct:** The eligible patients with heart disease who will be hospitalized in intensive care units of hospitals affiliated with Shahid Beheshti University of Medical Sciences during the study period will be enrolled into the trial. **Inclusion criteria:** Age of 20 to 75 years; acute coronary syndrome. **Exclusion criteria:** Olfactory disorder; asthma; allergy; psychiatric disorder; unconsciousness; ventricular tachycardia; ventricular fibrillation; cardiac resuscitation at the time of admission; having angina during interview; using herbal remedies in the past week. **Intervention group:** Aromatherapy with 4 drops of lemon balm placebo (sesame oil) for half an hour twice a day for 3 days. **Control group:** Aromatherapy with 4 drops of sesame oil (placebo) for half an hour twice a day for 3 days. **Primary outcome:** Assessing anxiety using the Spiel Berger standard questionnaire before and immediately after intervention. **Randomization:** Random assignment of the patients to the intervention and control groups through drawing of lots. **Blinding:** Patients will be unaware of the type of intervention. Therefore, the trial will be run as single blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201709219014N188**
Registration date: **2017-09-26, 1396/07/04**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-09-26, 1396/07/04

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research and Technology, Shahid
Beheshti University of Medical Sciences

Expected recruitment start date

2016-12-10, 1395/09/20

Expected recruitment end date

2017-02-28, 1395/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of aromatherapy with lemon balm versus placebo (sesame oil) on anxiety of patients with heart disease hospitalized in intensive care units: a single blind randomized clinical trial

Public title

Effect of aromatherapy with lemon balm versus placebo (sesame oil) on anxiety of patients with heart disease hospitalized in intensive care units

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age of 20 to 75 years; acute coronary syndrome. Exclusion criteria: Olfactory disorder; asthma; allergy; psychiatric disorder; unconsciousness; ventricular tachycardia; ventricular fibrillation; cardiac resuscitation at the time of admission; having angina during interview; using herbal remedies in the past week.

Age

From **20 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

Randomization: Random assignment of the patients to the intervention and control groups through drawing of lots. Blinding: Patients will be unaware of the type of intervention. Therefore, the trial will be run as single blind.

Secondary Ids

empty

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

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Shahid Beheshti University of Medical Sciences, Danshjou Bul.

City

Tehran

Postal code**Approval date**

2016-07-18, 1395/04/28

Ethics committee reference number

IR.SBMU.PHNM.1395.485

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

Acute coronary syndrome

ICD-10 code

I24.9

ICD-10 code description

Acute ischaemic heart disease, unspecified

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

Assessing anxiety

Timepoint

Before and immediately after intervention

Method of measurement

Using the Spiel Berger standard questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Aromatherapy with 4 drops of lemon balm placebo (sesame oil) for half an hour twice a day for 3 days.

Category

Treatment - Drugs

2**Description**

Control group: Aromatherapy with 4 drops of sesame oil (placebo) for half an hour twice a day for 3 days.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Hospitals affiliated with Shahid Beheshti University of Medical Sciences

Full name of responsible person

Adeleh Lotfi

Street address

School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences, Danshjou Bul.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research and Technology, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

Street address

Shahid Beheshti University of Medical Sciences, Danshjou Bul.

City

Tehran

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 and Technology, Shahid Beheshti 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**Name of organization / entity**

School of Nursing and Midwifery

Full name of responsible person

Adeleh Lotfi

Position

Nursing Student

Other areas of specialty/work**Street address**

School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences, Danshjou Bul.

City

Tehran

Postal code**Phone**

+98 21 2243 9770

Fax**Email**

adelelotfi842@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

School of Nursing and Midwifery

Full name of responsible person

Adeleh Lotfi

Position

Nursing Student

Other areas of specialty/work**Street address**

School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences, Danshjou Bul.

City

Tehran

Postal code**Phone**

+98 21 2243 9770

Fax**Email**

adelelotfi842@yahoo.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Department of Epidemiology

Full name of responsible person

Dr Jalal Poorolajal

Position

Associate Professor

Other areas of specialty/work**Street address**

School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code**Phone**

+98 81 3838 0090

Fax**Email**

poorolajal@umsha.ac.ir

Web page address

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