Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

Comparative Effectiveness of Lavender and Almond oil odor aroma therapy On Anxiety and Depression Patients Admitted to the cardiac intensive care unit

Protocol summary

Summary

Objective: To determine the effect of aromatherapy on anxiety and depression in patients with Khdvs Astv cardiac ICU study design: randomized, single-blind, placebo-controlled, phase 2 clinical trial Study population: patients admitted to the cardiac intensive care unit standards Help with anxiety and depression over 7-based tools HADS, age ≥ 18 years, patients with a diagnosis of ischemic heart disease, angina and myocardial infarction, non-allergic to flowers and plants or any allergy season Exclusion criteria: Cancel the patient continued study to heart failure and grade 3 or 4, discharge, death or transfer of the patient prior to the completion of the study, creating a situation of stress new interventions: a period of two days, starting at 11 am, use 2 drops of essential oil of Lavender along collar, Filled out questionnaires assessing anxiety and DEPRESION before the intervention, an hour later, 9 hours after the intervention period: Beginning in January 1391 the first case of primary outcome: length of hospital stay in patients' levels of anxiety and depression in

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012111711498N1**
Registration date: **2014-06-04, 1393/03/14**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-06-04, 1393/03/14

Registrant information

Name

Mohamad Nategh

Name of organization / entity

Shahed University

Country

Iran (Islamic Republic of)

Phone

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Email address

m.n1359@mihanmail.ir

Recruitment status

Recruitment complete

Funding source

shahed University

Expected recruitment start date

2012-12-21, 1391/10/01

Expected recruitment end date

2013-04-21, 1392/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Effectiveness of Lavender and Almond oil odor aroma therapy On Anxiety and Depression Patients Admitted to the cardiac intensive care unit

Public title

Lavender Aromatherapy in the Treatment of Anxiety And Dpression

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criteria:Having high anxiety and depression scores of 7 tools HADS,Age over 18 years , Patients with

a diagnosis of ischemic heart disease, angina and myocardial infarction,No risk of cardiogenic shock, having very poor medical condition, according to doctors at the hospital, Agree attract physicians to enter patients into the study, no pacemaker, no use of complementary therapies (herbal treatments, traditional and other therapies) in a week, no history of psychiatric disorders or being treated for anxiety and depression, lack of drug abuse, no history of asthma, eczema. Exclusion criteria included: patient withdrew from the study, grade 3 or 4 heart failure, discharge, or transfer the patient died before the completion of the study, a new stressful situations

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **110**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
shahed university

Street address
tehran-around heram emam khomani

City
tehran

Postal code
345627-367480

Approval date
2013-06-29, 1392/04/08

Ethics committee reference number
175283/41

Health conditions studied

1

Description of health condition studied
ANXEITY AND DEORESION

ICD-10 code
(F00-F99)

ICD-10 code description
Neurotic, stress-related and somatoform disorders

Primary outcomes

1

Description
Anxiety

Timepoint
Before the experiment, a time period of 2 days, 9 hours after the intervention.

Method of measurement
HADS, Hospital Anxiety and Depression questionnaire

2

Description
DEPRESSION

Timepoint
Before the experiment, a time period of 2 days, 9 hours after the intervention.

Method of measurement
HADS, Hospital Anxiety and Depression questionnaire

Secondary outcomes

1

Description
Blood pressure

Timepoint
Before the study, an hour later, 9 hours after the study

Method of measurement
Each patient monitoring devices over

2

Description
PULSE

Timepoint
Before the study, an hour later, 9 hours after the study

Method of measurement
Each patient monitoring devices over

Intervention groups

1

Description
Groups: first test: questions HADS (half hour before intervention) starting around 11 am instill 2 drops essential oil of Lavender by interfering emitters connected to a collar on paper and asking the patient to breathe normally for pin 20 minutes , second measurement: a questionnaire for a second time (an

hour later at 12 noon) measured a third time: for a third time to complete the questionnaire (at 8 pm) Continued intervention: at night before bed about 10 pm for another intervention (instill 2 drops Lavender essential oil) is applied to the patient. Fourth assessment: questionnaire for the fourth time in the morning when you wake up (Hdvdsat 7) days after the same has been repeated for patients at the end of the second day and morning of the third day measurements will be performed. Intervention in the control group will be the same except that instead of a drop of Lavender essential oil is used almond oil odorless.

Category

Treatment - Drugs

2

Description

Groups:placebo test: questions HADS (half hour before intervention) starting around 11 am instill 2 drops essential oil of Lavender by interfering emitters connected to a collar on paper and asking the patient to breathe normally for pin 20 minutes , second measurement: a questionnaire for a second time (an hour later at 12 noon) measured a third time: for a third time to complete the questionnaire (at 8 pm) Continued intervention: at night before bed about 10 pm for another intervention (instill 2 drops Lavender essential oil) is applied to the patient. Fourth assessment: questionnaire for the fourth time in the morning when you wake up (Hdvdsat 7) days after the same has been repeated for patients at the end of the second day and morning of the third day measurements will be performed.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospital Shiraz namazi

Full name of responsible person

MOHAMD NATEGH

Street address

Zand St., Shiraz

City

SHIRAZ

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed Univer Sity

Full name of responsible person

Mohamad Reza hiedari

Street address

Tehran, iran, Freeway persian golf

City

Tehran

Grant name

124554-12

Grant code / Reference number

15ن-22ت

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahed Univer Sity

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

Shahed University

Full name of responsible person

Mohammad Reza Heydari

Position

Ph.D. in Nursing

Other areas of specialty/work

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Full name of responsible person

ABBASE EBADI

Position

PHD NURSING

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MOHAMAD NATEGH
Position
Master of Nursing
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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