

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 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 Khdv 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  $\geq 18$  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 DEPRESSION 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

+98 21 5121 3134

##### 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-22ن

#### 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

##### Street address

Asr intersection of Taleghani - School of Nursing in SHAHED

##### City

Tehran

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002166418590

##### Phone

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

The University's OF Baghiatollah

##### Full name of responsible person

ABBASE EBADI

##### Position

PHD NURSING

##### Other areas of specialty/work

##### Street address

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
UNIVERSITY OF SHAHED  
**Full name of responsible person**  
MOHAMAD NATEGH  
**Position**  
Master of Nursing  
**Other areas of specialty/work**  
**Street address**  
Asr intersection of Taleghani , School of Nursing in  
SHAHED  
**City**  
TEHRAN  
**Postal code**

## 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*