

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 2026

### Comparison of lavender and Rosa Damascena scents on anxiety and vital signs of patients under coronary artery Angiography

#### Protocol summary

##### Summary

Objective: Comparison of lavender and Rosa Damascena scents on anxiety and vital signs of patients under coronary artery Angiography. Design: A clinical trial, single-center, randomized (block). How do: study in four groups: lavender, damask rose, placebo and control is performed. In this single-blind study, patients and the analyzed individual who does not have the kind of intervention. Inclusion criteria: age 35-70 years, alert, a healthy sense of smell; no drugs, anti-anxiety and depression in the past year, the non-occurrence of a traumatic event over a month before the intervention; angiography for the first time. Exclusion criteria: the history of asthma, bronchitis, chronic respiratory diseases, sensitivity to smell fragrant essential oils, drug addiction, mental disorders, angiography for acute myocardial infarction, hemodynamic disorder. Intervention: The intervention in two groups of aromatherapy with lavender and damask rose essential oil (with a concentration of 100% herbal medicines provided by companies Barij Essence Kashan) used separately, So that patients don't have Information from intervention. Essential to the hours of 22 to 6 am on angiography in patients and at a rate of two drops on a piece of gauze 2 × 2 has been attached to his collar. For intervention in the placebo group, from 22 hours to 6 am on angiography in patients and at a rate of three drops of water in a small glass container will be placed at a distance of 1 m from the patient. The main outcome variables: anxiety patients underwent coronary angiography.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017011325732N11**

Registration date: **2017-02-15, 1395/11/27**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-02-15, 1395/11/27

##### Registrant information

###### Name

Alireza Emadi

###### Name of organization / entity

Semnan University of Medical Sciences, Semnan, Iran

###### Country

Iran (Islamic Republic of)

###### Phone

+98 23 3345 1336

###### Email address

are20935@semums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Semnan University of Medical Sciences, Deputy of Research and Technology.

##### Expected recruitment start date

2016-11-21, 1395/09/01

##### Expected recruitment end date

2017-03-21, 1396/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of lavender and Rosa Damascena scents on anxiety and vital signs of patients under coronary artery Angiography

##### Public title

Comparison of lavender and Rosa Damascena scents on anxiety and vital signs of patients under coronary artery

Angiography

#### **Purpose**

Prevention

#### **Inclusion/Exclusion criteria**

Inclusion criteria: age 35-70 years, alert, a healthy sense of smell; no drugs, anti-anxiety and depression in the past year, the non-occurrence of a traumatic event over a month before the intervention; angiography for the first time. Exclusion criteria: the history of asthma, bronchitis, chronic respiratory diseases, sensitivity to smell fragrant essential oils, drug addiction, mental disorders, angiography for acute myocardial infarction, hemodynamic disorder.

#### **Age**

From **35 years** old to **70 years** old

#### **Gender**

Both

#### **Phase**

2

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **48**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Not blinded

#### **Blinding description**

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Ethics Committee, Deputy of research and technology, Semnan University of Medical Sciences

###### **Street address**

Semnan University of Medical Sciences, Basij Blvd, Semnan

###### **City**

Semnan

###### **Postal code**

3514799442

##### **Approval date**

2016-11-21, 1395/09/01

##### **Ethics committee reference number**

IR.SEMUMS.REC.1395.200

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Anxiety

##### **ICD-10 code**

F41.9

##### **ICD-10 code description**

Anxiety disorder, unspecified

### **Primary outcomes**

#### **1**

##### **Description**

Anxiety

##### **Timepoint**

Before intervention (before 22 hours) and immediately after the intervention (after 6 pm)

##### **Method of measurement**

Spielberger Anxiety Inventory

### **Secondary outcomes**

#### **1**

##### **Description**

blood pressure

##### **Timepoint**

Before intervention (before 22 hours) and immediately after the intervention (after 6 pm)

##### **Method of measurement**

Scorpions pressure Riester (Germany)

#### **2**

##### **Description**

heart beat

##### **Timepoint**

Before intervention (before 22 hours) and immediately after the intervention (after 6 pm)

##### **Method of measurement**

Touch the right wrist radial pulse

#### **3**

##### **Description**

Respiratory rate

##### **Timepoint**

Before intervention (before 22 hours) and immediately after the intervention (after 6 pm)

##### **Method of measurement**

See the chest

### **Intervention groups**

#### **1**

##### **Description**

The first intervention (aromatherapy with essential oils of lavender): Intervention for aromatherapy with lavender oil (with a concentration of 100% herbal medicines provided by companies Barij Essence Kashan) used.

Essential to the hours of 22 to 6 am on angiography in patients and at a rate of two drops on a piece of gauze 2 × 2 has been attached to his collar.

**Category**

Prevention

**2****Description**

The second intervention (aromatherapy with essential oils of damask rose): intervention for aromatherapy with essential oils of damask rose (with a concentration of 100% herbal medicines provided by companies Barij Essence Kashan) used. Essential to the hours of 22 to 6 am on angiography in patients and at a rate of two drops on a piece of gauze 2 × 2 has been attached to his collar.

**Category**

Prevention

**3****Description**

Third intervention (placebo): From 22 to 6 am on angiography in patients and at a rate of three drops of water in a small glass container will be placed at a distance of 1 m from the patient.

**Category**

Behavior

**4****Description**

Fourth intervention (control): patients only receive routine care without any additional intervention.

**Category**

N/A

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

Kosar Hospital

**Full name of responsible person**

Mohammad Reza Asgari

**Street address**

Kosar Hospital, BLVD Basij, Semnan

**City**

Semnan

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Semnan University of Medical Sciences, Deputy of Research and Technology.

**Full name of responsible person**

Ali Rashidy-Pour

**Street address**

Semnan University of Medical Sciences, Deputy of Research and Technology, Basij Blvd, Semnan

**City**

Semnan

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Semnan University of Medical Sciences, Deputy of Research and Technology.

**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**

Semnan University of Medical Sciences

**Full name of responsible person**

Mohammadreza Asgari

**Position**

PhD in nursing

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

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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*