

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Aromatherapy with Lavender on sleep quality patients

#### Protocol summary

##### Summary

The aim of this study is to determine the effect of aromatherapy with lavender on patients' sleep quality after coronary artery bypass surgery. This study is a clinical trial. The sample includes all male and female patients undergoing coronary artery bypass graft in Kowsar Hospital of the Semnan University of Medical Sciences. The main criterion for inclusion is adequate vigilance on the first day after coronary artery bypass graft surgery. The most important exclusion criterion is the patient's loss of consciousness. The sample size is estimated 30 people for each group and a total of 60 people. In order to carry out the research, the sleep quality of the patients will be measured by using hospital sleep quality questionnaire in the morning after surgery. At second night at 9pm, Lavender in the intervention group and the placebo in control group (distilled water) will be dropped on a cotton ball at a rate of 2 drops and will be kept in front of the patients' noses and they will be asked to breathe 10 times deeply and in the following, cotton ball will be attached to the patients' clothes by using a pin and will be attached to his collar until 8 am. This process will be done for both groups of patients for 3 days. Then the difference between the initial sleep score and calculated sleep score will be calculated after the intervention in both groups. Finally, the difference between the scores of the two groups will be compared

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017060811399N6**

Registration date: **2017-06-12, 1396/03/22**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-06-12, 1396/03/22

##### Registrant information

###### Name

Abbasali Ebrahimian

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 25 3107 1082

###### Email address

ebrahimian.aa@gmail.com

##### Recruitment status

###### Recruitment complete

##### Funding source

Semnan University of Medical Sciences

##### Expected recruitment start date

2017-07-23, 1396/05/01

##### Expected recruitment end date

2018-03-20, 1396/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Aromatherapy with Lavender on sleep quality patients

##### Public title

The Effect of aromatherapy with Lavender on sleep quality among patients undergoing Coronary Artery Bypass Graft in Semnan Kowsar Hospital

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: The patients' willingness to participate in the study; Undergoing non-emergency open heart surgery for the first time; Aged between 30 and 75 years old; Stable hemodynamic condition such as systolic

blood pressure higher than 90 mmHg; lack of life threatening dysrhythmia and a heart rate between 60 and 100 bpm; Not drug and alcohol addicted; lack of confirmed mental illness; No history of known allergies to lavender or seasonal allergy; lack of olfactory disorders; Lack of respiratory disorders such as asthma; Being conscious and oriented to time; Place and person and having the ability to complete hearing and speech. Exclusion criteria: Taking the sedative in addition to routine treatments; life threatening dysrhythmias or any emergency conditions requiring immediate intervention; loss of the patient's consciousness; The patient's willingness to quit from the study; allergy to lavender or any allergic reaction during the study.

#### **Age**

From **30 years** old to **75 years** old

#### **Gender**

Both

#### **Phase**

N/A

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

*No information*

#### **Sample size**

Target sample size: **60**

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

Randomized

#### **Randomization description**

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

Not blinded

#### **Blinding description**

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

Barij Essence company lavender essential oil will be used in this study.

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

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

Ethic committee of Semnan University Of Medical science

##### **Street address**

Vice chancellor for research, Semnan University of Medical Sciences, Basij Blvd

##### **City**

Semnan

##### **Postal code**

##### **Approval date**

2017-05-21, 1396/02/31

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

IR.SEMUMS.REC.1396.14

## **Health conditions studied**

### **1**

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

Sleep disorder

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

G47.0

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

Disorders of initiating and maintaining sleep [insomnias]

## **Primary outcomes**

### **1**

#### **Description**

Patients sleep quality after coronary artery bypass graft

#### **Timepoint**

Daily, during 4 days

#### **Method of measurement**

Hospital sleep quality questionnaire

## **Secondary outcomes**

### **1**

#### **Description**

Sleep quality after water inhalation

#### **Timepoint**

Daily, during 4 days

#### **Method of measurement**

Hospital sleep quality questionnaire

## **Intervention groups**

### **1**

#### **Description**

In the intervention group, Lavender will be dropped on a cotton ball at a rate of 2 drops and Will be kept in front of the patient's nose and patients will be asked to breathe 10 time deeply and in the following, cotton ball will be attached to the patient's clothes by using a pin and will be attached to his collar until 8 am, Then it will be separated from the patient's clothes and will be discarded. This process will be done for patients for 3 days. After each intervention, the previous night sleep quality of the patient will be assessed by using Hospital Sleep Quality Questionnaire.

#### **Category**

Treatment - Other

### **2**

#### **Description**

In the control group, distilled water will be dropped on a cotton ball at a rate of 2 drops and will be kept in front of the patient's nose and he will be asked to take 10 deep breaths and in the following, cotton ball will be attached to the patient's clothes by using a pin and will be attached to his collar until 8 am, Then it will be

separated from the patient's clothes and will be discarded. This process will be done for patient for 3 days. After each intervention, the previous night sleep quality of the patient will be assessed by using Hospital Sleep Quality Questionnaire.

**Category**

Placebo

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

Kowsar Hospital

**Full name of responsible person**

Dr Majid Mirmohammad-Khani

**Street address**

1 th Floor, Vice chancellor for research, Kowsar Hospital, Basij Blvd

**City**

Semnan

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

Vice chancellor for research, Semnan University of Medical Sciences

**Full name of responsible person**

Dr Ali Rashidi-Pour

**Street address**

Vice chancellor for research, Semnan University of Medical Sciences, Basij Blvd

**City**

Semnan

**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, Semnan 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**

Semnan University of Medical Sciences

**Full name of responsible person**

Hossein Davari

**Position**

Msc in critical care nursing

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

Msc in critical care nursing

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**Full name of responsible person**

Abbasali Ebrahimian

**Position**

PhD of Health in Emergencies and Disasters

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ebrahimian.aa@gmail.com

**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*