

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### Comparison of the effects of aromatherapy with essential oils of lavender and valerian on pain and anxiety in patients undergoing coronary artery bypass graft (CABG)

#### Protocol summary

##### Summary

This study aims to compare the effect of lavender and valerian essential oil on pain and anxiety after coronary artery Bypass Graft (CABG) surgery. In this study, patients undergoing CABG who admitted to Surgical ICU Department, at Fatemeh Al Zahra Hospital, affiliated by Mazandaran University of Medical Sciences will be studied. Inclusion criteria include being at the age of 35-70 years, complete consciousness, healthy sense of smell, and absence of drug addiction. Selected samples will be assigned into three groups of 28 participants including lavender, valerian, and placebo according to age and sex and through randomized block design. On second day after CABG in the evening shifts and after 3 hours of the last dose of the analgesics injection, pain will be measured using a Visual Analog Scale (VAS) questionnaire and anxiety will be measured using Spielberger state- trait anxiety inventory before intervention and then, intervention will be performed according to the designated group. In lavender and valerian group, three drops of essential oil will be poured on cotton and all of this will be placed in an oxygen mask and oxygen therapy with a mask (5-6 liters per minute) will be performed for 15 minutes. In the placebo group instead of the essential oil, three drops of distilled water will be poured on cotton and will be placed in an oxygen mask and oxygen therapy with a mask (5-6 liters per minute) will be performed for 15 minutes. Then the pain intensity will be measured at 5, 30, and 60 minutes after the intervention. The patients' anxiety will be measured one hour after the intervention with Spielberger's state anxiety inventory.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201708016342N6**

Registration date: **2017-08-31, 1396/06/09**

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

Last update:

Update count: **0**

##### Registration date

2017-08-31, 1396/06/09

##### Registrant information

###### Name

Ali Asghar Ghods

###### Name of organization / entity

Semnan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 23 1335 4192

###### Email address

aaghods@sem-ums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Semnan University of Medical Sciences

##### Expected recruitment start date

2017-08-23, 1396/06/01

##### Expected recruitment end date

2017-12-22, 1396/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effects of aromatherapy with essential oils of lavender and valerian on pain and anxiety in patients undergoing coronary artery bypass graft (CABG)

## Public title

Effects of aromatherapy on pain and anxiety

## Purpose

Supportive

## Inclusion/Exclusion criteria

Inclusion Criteria: Patient consent to participate in the study; age 35-70 years; having spontaneous breathing; complete consciousness; healthy sense of smell; no history of asthma and allergy to plants; lack of drug addiction; not treated with anti-anxiety and depression drugs; surgery of Coronary artery bypass graft is not an emergency; having no pulmonary and obstructive disease. Exclusion Criteria: Unwillingness to continue to participate in the study; the severe complications of coronary artery bypass graft surgery; the patient's pain before the study is zero

## Age

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

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **84**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Semnan University of Medical Sciences

##### Street address

Semnan University of Medical Sciences, Basij blvd, Semnan

##### City

Semnan

##### Postal code

#### Approval date

2017-07-12, 1396/04/21

## Ethics committee reference number

IR.SEMUMS.REC.1396.63

## Health conditions studied

### 1

#### Description of health condition studied

ischaemic heart disease

#### ICD-10 code

I25.1

#### ICD-10 code description

Atherosclerotic heart disease

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

before intervention; 5, 30 and 60 minute after intervention

#### Method of measurement

Pain Visual analogue scale

### 2

#### Description

Anxiety

#### Timepoint

Before and after intervention

#### Method of measurement

Speilberger anxiety questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

three drops of valerian essential oil will be poured on cotton and all of this will be placed in an oxygen mask and oxygen therapy with a mask (5-6 liters per minute) will be performed for 15 minutes

#### Category

Prevention

### 2

#### Description

three drops of lavender essential oil will be poured on cotton and all of this will be placed in an oxygen mask and oxygen therapy with a mask (5-6 liters per minute) will be performed for 15 minutes

#### Category

Prevention

### 3

#### Description

three drops of distilled water will be poured onto cotton and will be placed in an oxygen mask and oxygen therapy with a mask (5-6 liters per minute) will be performed for 15 minutes

#### Category

Placebo

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Fateme-Al-Zahra hospital

###### Full name of responsible person

Abbas Keramati

###### Street address

Fateme-Al-Zahra hospital, Artesh Boulevard, Sari, Iran

###### City

Sari

### 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

Semnan University of Medical Sciences, Basij Boulevard, Semnan, Iran

###### 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

Dr. Ali Asghar Ghods

#### Position

Faculty Member

#### Other areas of specialty/work

#### Street address

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### Person responsible for updating data

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**Fax**  
**Email**  
**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*