

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### The effect of *Melissa officinalis* on sleep quality and anxiety in patients who suffer from acute coronary syndrome

#### Protocol summary

##### Summary

Objective: Determination of the effect of *Melissa officinalis* on sleep quality and anxiety in patients who suffer from acute coronary syndrome -Design: randomized double-blind, placebo-controlled trial - Inclusion criteria: patients (male, female) with acute coronary syndrome; age 30 to 80 years old; Patient's willingness to participate in the study; being fully alert and able to communicate; having no history of sleep disturbance before admission; having no history of chronic pain; alcoholism; drug use; COPD and sleep apnea. -Exclusion criteria: not willing to continue co-operation with the study; death -Sample size: 72 - Intervention: Case group receives 2 grams *Melissa officinalis* (4 capsules contains 500 mg *Melissa officinalis* daily) for 7 days and control group receives 2 grams starch powder daily (4 capsules contains 500 mg starch powder daily) for 7 days. - Outcomes: *Melissa officinalis* is expected to improve the quality of sleep and anxiety of patients with acute coronary syndrome in the CCU.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017070234851N1**  
Registration date: **2017-08-21, 1396/05/30**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-08-21, 1396/05/30

##### Registrant information

##### Name

Maryam Emami

##### Name of organization / entity

Faculty of Nursing and Midwifery Shahed

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6641 8587

##### Email address

m.emami@shahed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shahed University

##### Expected recruitment start date

2017-08-11, 1396/05/20

##### Expected recruitment end date

2018-01-20, 1396/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of *Melissa officinalis* on sleep quality and anxiety in patients who suffer from acute coronary syndrome

##### Public title

*Melissa officinalis* effect on sleep quality and anxiety in patients with acute coronary syndrome

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Entry criteria: company in the study; patients tend to benefit from mental health; not having the experience of sleep disorder before bed; having full consciousness and able to communicate; having no history of chronic pain; addiction to alcohol and drugs; having at least 30 years of age up to 80; the first patient to be hospitalized; the ability to turn taking medication orally; the history of

Sleep apnea and COPD; while according to the rating criteria for differentiating diagnosis of Pittsburgh sleep disorder questionnaire before bed with sleep disturbances caused by the patient's hospitalization if you get 0-4 points will be studied; the history of PCI. Exit criteria: cancel the patient's continued cooperation; the patient's feet

#### **Age**

From **30 years** old to **80 years** old

#### **Gender**

Both

#### **Phase**

N/A

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

*No information*

#### **Sample size**

Target sample size: **72**

#### **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**

Shahed University

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

Shahed University, In front of Imam Khomeini(ra)'s holy shrine, First of Tehran\_Qom free way

###### **City**

Tehran

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

3319118651

###### **Approval date**

2017-07-19, 1396/04/28

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

IR.Shahed.REC.1396.21

### **Health conditions studied**

#### **1**

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

Acute coronary syndrome

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

I24.9

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

Acute ischaemic heart disease, unspecified

### **Primary outcomes**

#### **1**

##### **Description**

Sleep quality

##### **Timepoint**

before intervention- at the end of intervention

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

Richards-Campbell Sleep Questionnaire (RCSQ)

#### **2**

##### **Description**

Anxiety

##### **Timepoint**

before intervention- at the end of intervention

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

Spielberger State-Trait Anxiety Inventory (STAI)

### **Secondary outcomes**

#### **1**

##### **Description**

The side effects of medication

##### **Timepoint**

before intervention- at the end of intervention

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

Side effects form of medication

### **Intervention groups**

#### **1**

##### **Description**

Case group receives 2 grams Melissa Officinalis (4 capsules contains 500 mg Melissa Officinalis daily) for 7 days

##### **Category**

Treatment - Drugs

#### **2**

##### **Description**

control group receives 2 grams starch powder daily (4 capsules contains 500 mg starch powder daily) for 7 days

##### **Category**

Treatment - Drugs

### **Recruitment centers**

#### **1**

##### **Recruitment center**

###### **Name of recruitment center**

Hospital of Valiasr Qom, CCU

###### **Full name of responsible person**

Maryam Emami, MSc Student of critical care Nursing  
**Street address**  
Islamic Republic Blvd, Amin Blvd, Qom  
**City**  
Qom

m.emami@shahed.ac.irm.emami7727@gmail.ir  
**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shahed University

**Full name of responsible person**

Mohammad Reza Heidari

**Position**

PhD in Nursing

**Other areas of specialty/work**

**Street address**

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heidari43@yahoo.com

**Web page address**

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Shahed University

**Full name of responsible person**

Dr.Zahra Kiasalar(Vice President of Research)

**Street address**

Shahed University, In front of Imam Khomeini(ra)'s  
holy shrine, First of Tehran\_Qom free way

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Shahed University

**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**

Faculty of Nursing and Midwifery Shahed

**Full name of responsible person**

Maryam Emami

**Position**

MSc Student of critical care Nursing

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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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*