

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### The effect of combined aromatherapy on sleep quality in hospitalized patients with Acute coronary syndrome (ACS) in cardiac care unit

#### Protocol summary

##### Summary

The aim of this study is to examine the effect of combined aromatherapy on sleep quality in hospitalized patients with ACS in cardiac care unit. 60 patients hospitalized in coronary care units of 22 Bahman Hospital in Gonabad, will be selected and divided into control and experimental groups randomly. All the samples will sign the Informed Consent form; Then, the Hospital Sleep Questionnaire will be completed before and after intervention by a person who is not aware of control and experimental groups. Three consecutive nights at 09:00 pm, with the supervision of researchers, patients will be exposed to a combination of essential oils of lavender, chamomile and neroli, with 6, 2, 0.5 ratio. Essential oil will be dropped on a cotton ball, then the Cotton will be hold near the nose of the patients and ask them to close their eyes and take ten deep breaths. After that the cotton will be attached to the patient's collar by a pin and detached after waking up. There will be no intervention in the control group. The patients' sleep quality will be measured by the Hospital Sleep Questionnaire "VSH".

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015122922682N4**

Registration date: **2016-05-28, 1395/03/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-05-28, 1395/03/08

##### Registrant information

Name

Mahsa Moazzen Ahmadi

##### Name of organization / entity

Gonabad University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 5722 3514

##### Email address

moazzenm2@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Gonabad University of Medical Sciences

##### Expected recruitment start date

2016-04-13, 1395/01/25

##### Expected recruitment end date

2016-05-14, 1395/02/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of combined aromatherapy on sleep quality in hospitalized patients with Acute coronary syndrome (ACS) in cardiac care unit

##### Public title

The effect of combined aromatherapy on sleep quality in cardiac patients

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Hospitalized patients with the clinical diagnosis of heart disease in intensive coronary care unit; Having a strong natural tendency for cooperation in doing some medical research and signing the Informed

consent form for research; Stable vital signs (blood pressure, pulse, respiration, temperature); Patients' age over 30 and under 80 years; Having no allergic histories to medicines and all herbs (Herbal Medicines or Herbal remedies). Exclusion criteria: Patient transfer from the Cardiac Care Unit to the other wards; To be discharged from the hospital either doctor's order or against medical advice; The patient's unwillingness to continue his or her cooperation in the study; Indication of allergy symptoms.

#### 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: **60**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

Samples based on permutation blocks (four blocks) will be divided into two experimental and control groups. It will be listed according to six possible ways (AABB, ABAB, ...) randomly that will determine the required number of blocks and arrange them into groups based on experimental (B) and control (A). For blinding the questionnaire will be completed by a person who is not aware of the research unit in the control group or the experimental group.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Gonabad University of Medical Sciences

##### Street address

Gonabad University of Medical Sciences

##### City

Gonabad

##### Postal code

9691711111

#### Approval date

2015-12-23, 1394/10/02

#### Ethics committee reference number

IR.GMU.REC.1394.61

## Health conditions studied

### 1

#### Description of health condition studied

Sleep Quality

#### ICD-10 code

G47.9

#### ICD-10 code description

Sleep disorder, unspecified

## Primary outcomes

### 1

#### Description

Sleep Quality

#### Timepoint

2 hours before intervention, 3 days after intervention

#### Method of measurement

Verran and Snyder-Halpern Sleep Scale (VSH Sleep Scale)

## Secondary outcomes

### 1

#### Description

Sensitivity to essences

#### Timepoint

2 hours before intervention, every 3 hours during intervention and 2 hours after intervention

#### Method of measurement

Clinical signs and symptoms

## Intervention groups

### 1

#### Description

Intervention group: For three consecutive nights at 09:00 pm, with the supervision of researchers, patients will be exposed to a combination of essential oils of lavender, chamomile and neroli, with 6, 2, 0.5 ratio. A Pharmaceutical company will prepare them in Gorgan. Essential oil will be dropped on a cotton ball, then the Cotton will be hold near the nose of the patients and ask them to close their eyes and take ten deep breaths. After that the cotton will be attached to the collar of the patient by a pin and detached after waking up. The standard Hospital Sleep Questionnaire, Verran and Snyder-Halpern will be completed before and after the intervention.

#### Category

Treatment - Other

### 2

#### Description

Control group: During the three nights of stay in the ward only routine treatments will be carried out without any

intervention by the researchers. The Standard Hospital Sleep Questionnaire, Verran and Snyder-Halpern will be completed before and after.

**Category**

Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

22 Bahman Hospital

**Full name of responsible person**

Dr. Mahmod Reza Nematollahi

**Street address**

22 Bahman Hospital, Naserkhosro Street, Gonabad, Iran

**City**

Gonabad

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice Chancellor for Research, Gonabad University of Medical Sciences

**Full name of responsible person**

Dr. Ali Mohammadpour

**Street address**

Vice chancellor for research, Gonabad University of Medical Sciences, Gonabad

**City**

Gonabad

**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, Gonabad 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**

Gonabad University of Medical Sciences

**Full name of responsible person**

Hosein Aalami

**Position**

Critical Care Nursing Graduate Student

**Other areas of specialty/work**

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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*