

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Effect of Rosa damascene aromatherapy on sleep quality in cardiac Care unit patients in Shahid Mohammadi Hospital in Bandar Abbas

#### Protocol summary

##### Summary

Objectives: To evaluate the effects of Rose aromatherapy on sleep quality in ccu patients. Inclusion criteria: Know the time; place ; person, the heart's ejection fraction is at least 40%,Not disturbing sleep disorders (such as migraines and arthritis);not a history of asthma; allergies to certain floral notes; not Orthopnea.Exclusion criteria: Patient is short of breath; leaves; dies; not desire to continue. The study population: Cardiac Care Unit patients. Shahid Mohammadi Hospital in Bandar Abbas on the intervention and control groups were divided randomly into two. Sample size: 60 patients (30 Control, 30 Case) .Intervention studied and time: the implementation of the study is three consecutive nights for each patient. Rose Aromatherapy is performed every night at 22 to 6 am by sleep quality Index Pittsburgh before and after, in both groups .compare the quality of patients' sleep: sleep quality parameters including subjective sleep quality, ,sleep latency,sleep duration,habitual sleep efficiency,sleep disturbances, use of sleeping medication ,daytime dysfunction initial. The primary outcome: stimulates the central nervous system and beta-endorphin

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016062628659N1**

Registration date: **2016-07-05, 1395/04/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-07-05, 1395/04/15

##### Registrant information

##### Name

Foroogh Ziarati

##### Name of organization / entity

Hormozgan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3832 0311

##### Email address

foroogh.ziarati128@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

Hormozgan University of Medical Sciences

##### Expected recruitment start date

2016-04-20, 1395/02/01

##### Expected recruitment end date

2016-06-21, 1395/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Rosa damascene aromatherapy on sleep quality in cardiac Care unit patients in Shahid Mohammadi Hospital in Bandar Abbas

##### Public title

Effect of Rosa damascene aromatherapy on sleep quality in CCU patients in Shahid Mohammadi Hospital in Bandar Abbas Effect of Rosa damascene aromatherapy on quality of sleeping in cardiac Care unit patients in Shahid Mohammadi hospital in Bandar Abbas

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: know the time; place ; person, the

heart's ejection fraction is at least 40%,Not disturbing sleep disorders (such as migraines and arthritis);not a history of asthma; allergies to certain floral notes; not Orthopnea. Exclusion criteria: patient is short of breath; leaves; dies; not desire to continue.

**Age**

No age limit

**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****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee, Hormozgan University of Medical Sciences, Bandar Abbas, Iran.

**Street address**

First Floor, Research Center, East Side of Hospital, Shahid Mohammadi Hospital, Jomhuri Eslami Boulevard, Bandar Abbas

**City**

Bandar Abbas

**Postal code****Approval date**

2016-02-04, 1394/11/15

**Ethics committee reference number**

HUMS.REC.1394.97

**Health conditions studied****1****Description of health condition studied**

Sleep Disorders and Heart Disease

**ICD-10 code**

G47

**ICD-10 code description**

Sleep Disorders

**Primary outcomes****1****Description**

Parameters of Sleep Quality( subjective sleep quality,sleep latency,sleep duration,habitual sleep efficiency,sleep disturbances, use of sleeping medication ,daytime dysfunction)

**Timepoint**

2 months

**Method of measurement**

Pittsburgh Sleep Quality Index

**Secondary outcomes****1****Description**

Improve Sleep Quality

**Timepoint**

2 months

**Method of measurement**

Pittsburgh Sleep Quality Index

**Intervention groups****1****Description**

Receive standard treatment prescribed by a cardiologist. Moreover, the use of placebo

**Category**

Placebo

**2****Description**

Receive standard treatment prescribed by a cardiologist. The use of semi-solid oil rose at the same time. Dose: a Gram.Time use: Three consecutive nights .How use: Aromatherapy

**Category**

Treatment - Drugs

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

Shahid Mohammadi Hospital, Cardiac Care Unit

**Full name of responsible person**

Forough Ziarati

**Street address**

Shahid Mohammadi Hospital, Jomhuri Eslami Boulevard, Bandar Abbas

**City**

Bandar Abbas

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Hormozgan University of Medical Sciences

**Full name of responsible person**

Forough Ziarati

**Street address**

First Floor, Research Center, East Side of Hospital,  
Shahid Mohammadi Hospital, Jomhuri Eslami  
Boulevard, Bandar Abbas

**City**

Bandar Abbas

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

Yes

**Title of funding source**

Hormozgan 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**

Student Research Committee, Hormozgan University  
of Medical Sciences, Bandar Abbas

**Full name of responsible person**

Forough Ziarati

**Position**

Student

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

Research Center, East Side of Hospital, Shahid  
Mohammadi Hospital, Jomhuri Eslami Boulevard,  
Bandar Abbas

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## Person responsible for scientific

## inquiries

**Contact****Name of organization / entity**

Department of Nursing, Faculty of Nursing and  
Midwifery, Hormozgan University of Medical Sciences,  
B

**Full name of responsible person**

Fouziyeh Mokhtari

**Position**

MSC

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

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## Person responsible for updating data

**Contact****Name of organization / entity****Full name of responsible person**

Forough Ziarati

**Position**

Student

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Bandar Abbas

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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*