Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of Combined and Single Aromatherapy of Orange and Orange Blossom Extracts on Quality of Sleep in Patients with Acute Coronary Syndrome that Hospitalized in Cardiac Care Units of Selected Shahid Beheshti University of Medical Sciences; 2017

Protocol summary

Study aim

The comparison of the effect of combined and single aromatherapy of orange and orange blossom extracts on quality of sleep in patients with acute coronary syndrome that hospitalized in cardiac care units of selected Shahid Beheshti University of Medical Sciences; 2017

Design

The patients were randomized into 4 groups and Epworth quality of sleep scale was completed for all of them. Then, in each night, in intervention groups, 3 drops of orange blossom extract, orange extract and combined orange and orange blossom extract, administered on a cotton beside of the patient's pillow before the sleeping. The control group does not receive any intervention. The next morning, St. Mary's hospital sleep quality questionnaire (SMHSQ) completed for patients and last night quality of sleep was evaluated.

Settings and conduct

This study will be carried out at selected hospitals of Shahid Beheshti University of Medical Sciences with active CCU units.

Participants/Inclusion and exclusion criteria

The minimum of age is 30 years old Informed consent to participate in the study Hospitalized with the acute coronary syndrome in the cardiac care unit Minimum duration time of hospitalization is 24 hours The stability of vital signs Lack of known respiratory disease such as asthma Lack of sense of smell disorders Lack of mental disorder The addiction to drugs and alcohol Use of sedative and opioid drugs The history of eczema and allergy to herbals No consent to participate in the study Psychological crises such as depression, mourning and divorce

Intervention groups

Group 1: administration orange extract Group 2: administration orange blossom extract Group 3: administration the combined orange and orange blossom extracts Group 4: Control

Main outcome variables

sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170312033035N2**
Registration date: **2018-08-28, 1397/06/06**
Registration timing: **retrospective**

Last update: **2018-08-28, 1397/06/06**
Update count: **0**

Registration date

2018-08-28, 1397/06/06

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 915 532 5448

Email address

gharaee.r@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-07-23, 1397/05/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Combined and Single Aromatherapy of Orange and Orange Blossom Extracts on Quality of Sleep in Patients with Acute Coronary Syndrome that Hospitalized in Cardiac Care Units of Selected Shahid Beheshti University of Medical Sciences; 2017

Public title
The Effect of Combined and Single Aromatherapy of Orange and Orange Blossom Extracts on Quality of Sleep in Patients with the Acute Coronary Syndrome
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
The minimum of age is 30 years old. Written consent to enter the study Hospitalization of the patient with the diagnosis of acute coronary syndrome in cardiac care unit Passed at least 24 hours of hospitalization The stability of vital signs (Pulse, temperature, blood pressure, respiration) Not having known respiratory problems like asthma Lack of olfactory disorder Lack of mental illness
Exclusion criteria:
Drug Addiction and Alcohol Use of sedative and opiate drugs History of eczema and allergies to plants Dissatisfied with participating in the study The existence of psychological crises such as depression, mourning and divorce
Age
From **30 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomized
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of shahid beheshti University of Medical Sciences
Street address
Shahid Beheshti University of Medical Sciences, Velenjak Ave, Daneshgah Blvd
City
Tehran
Province
Tehran
Postal code
9519933449
Approval date
2018-02-04, 1396/11/15
Ethics committee reference number
IR.SBMU.RETECH.REC.1396.1196

Health conditions studied

1

Description of health condition studied
Sleep quality
ICD-10 code
F51
ICD-10 code description
Sleep disorders not due to a substance or known physiological condition

Primary outcomes

1

Description
Sleep disorder
Timepoint
12 hours after use
Method of measurement
Epworth Sleepiness Scale

Secondary outcomes

1

Description
Sleep quality
Timepoint
12 hours after Intervention
Method of measurement
St. Mary's Hospital Sleep Questionnaire (SMHSQ)

Intervention groups

1

Description

Intervention group: administration orange extract

Category

Rehabilitation

2

Description

Intervention group: administration orange blossom extract

Category

Rehabilitation

3

Description

Intervention group: administration the combined orange and orange blossom extracts

Category

Rehabilitation

4

Description

Intervention group: Control

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Hoseyn Hospital of Tehran

Full name of responsible person

Dr malek pur

Street address

Imam Hossein Square

City

Tehran

Province

Tehran

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9519933449

Phone

+98 21 7343 2338

Email

gharaee.r@sbmu.ac.ir

2

Recruitment center

Name of recruitment center

Shahid Modares Hospital of Tehran

Full name of responsible person

Dr Bande

Street address

Saadat Abad Street

City

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Province

Tehran

Postal code

1998734383

Phone

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Email

gharaee.r@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Rasool Gharaee

Street address

Shahid-e-Araabi Shahid Chamran Highway, Yemen Street, Shahid Beheshti University of Medical Sciences, Tehran, Iran

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9519933449

Phone

+98 21 8820 2518

Email

gharaee.r@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Rasool Gharaee

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Faculty of Nursing and Midwifery, Intersection of Valiasr Street and Nisa Highway, In front of Shahid Rajaee Heart Hospital

City
Tehran

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gharaee.r@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Sima Zohari

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Faculty of Nursing and Midwifery, Intersection of Valiasr Street and Niyayesh Highway , In front of Shahid Rajaee Heart Hospital

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
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City
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Province
Tehran

Postal code
9519933449

Phone
+98 21 8820 2518

Email
gharaee.r@sbmu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data will be able to share when unrecognize participants.

When the data will become available and for how long
Six months after printing results

To whom data/document is available
Researchers working in academia and scientific institues

Under which criteria data/document could be used
For systematic reviews and meta-analysis

From where data/document is obtainable
Email: gharaee.r@sbmu.ac.ir

What processes are involved for a request to access data/document
After Email reception.

Comments