Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of geranium aromatherapy on sleep quality and vital signs of coronary artery disease patients admitted to critical care units

Protocol summary

Study aim
Evaluation of the effect of geranium fragrance on sleep quality and vital signs of coronary artery patients admitted to cardiac intensive care units

Design
Randomized clinical trial, with a control group, parallel groups. The sample size is 60 patients that randomly will be assigned to control and intervention groups using the block randomization method.

Settings and conduct
This study will be performed in the critical care unites of Shahid Beheshti Hospital in Qom. In the aromatherapy group, three drops of Geranium essence will be poured on a tissue and pinned next to the patient's pillow so that they can inhale it from 10 pm to 6 am. In the control group, only routine care will be done, including teaching how to control anxiety and reduce ambient light and noise. Blinding will not be done in this study.

Participants/Inclusion and exclusion criteria
Hospitalization in cardiac intensive care unit and acute coronary syndrome

Intervention groups
The scent of geranium will be used for three nights for the patients of the intervention group.

Main outcome variables
Sleep quality, vital signs

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150724023314N5**
Registration date: **2022-11-16, 1401/08/25**
Registration timing: **prospective**

Last update: **2022-11-16, 1401/08/25**
Update count: **0**

Registration date
2022-11-16, 1401/08/25

Registrant information

Name
Mohammad Abbasinia

Name of organization / entity
Qom university of medical sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-11-21, 1401/08/30

Expected recruitment end date
2023-02-20, 1401/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of geranium aromatherapy on sleep quality and vital signs of coronary artery disease patients admitted to critical care units

Public title
The effect of geranium aromatherapy on sleep quality and vital signs of coronary artery disease patients

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Hoispitalization in the cardiac intensive care unit with a diagnosis of acute coronary syndrome

Exclusion criteria:

The patient refuses to participating in the study and Instability of the patient's vital signs

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

Participants will be assigned to intervention and control groups using block randomized method. The link "https://www.sealedenvelope.com/simple-randomiser/v1/lists" will be used for block randomization. For this purpose, the target number of samples (90 samples including sample loss), number of groups (two groups A and B) and number of blocks (4) will be entered and the system will provide the researcher with a list of 4 blocks. Based on the output list, it will be determined in which group the patients who enter the study should be placed in order. Items A represent the intervention group and items B represent the control groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qom University of Medical Sciences

Street address

Qom University of Medical Sciences, Saheli street, Qom.

City

Qom

Province

Ghoum

Postal code

3713649373

Approval date

2021-03-14, 1399/12/24

Ethics committee reference number

IR.MUQ.REC.1399.300

Health conditions studied

1

Description of health condition studied

Ischaemic heart diseases

ICD-10 code

I20-I25

ICD-10 code description

Ischaemic heart diseases

Primary outcomes

1

Description

Sleep quality

Timepoint

Three consecutive nights from 10 pm to 6 am

Method of measurement

Pittsburgh questionnaire

Secondary outcomes

1

Description

Vital signs

Timepoint

Immediately before and 10 min after intervention

Method of measurement

With vital signs monitoring devices

Intervention groups

1

Description

Intervention group: In the aromatherapy group, three drops of Geranium essence will be poured on a tissue and pinned next to the patient's pillow so that they can inhale it from 10 pm to 6 am.

Category

Other

2

Description

Control group: In the control group, only routine care will be done, including teaching how to control anxiety and reduce ambient light and noise.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Beheshti Hospital of Qom

Full name of responsible person
Mohammad Abbasinia

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Shahid Beheshti Hospital, Shahid Beheshti Boulevard, Qom

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ghoum University of Medical Sciences

Full name of responsible person
Dr. Alireza Kohpaei

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Grant name

Grant code / Reference number

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

Title of funding source
Ghoum 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
Ghoum University of Medical Sciences

Full name of responsible person
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Assistant Professor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available