

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Effect of aromatherapy with *Melissa officinalis* versus placebo on the sleep quality and physiological indicators in patients admitted at the cardiac care unit: a single-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of aromatherapy with *Melissa officinalis* versus placebo on the sleep quality and physiological indicators in patients admitted at the cardiac care unit

Design

This is a single-blind randomized clinical trial, phase II, in which 96 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients admitted at the cardiac care unit in Shahid Rajaei Hospital in Tehran City during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the drawing of lots. This trial will be single-blinded so that neither patients nor the physician who will examine the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 65 years, Sleep disorder
Exclusion criteria: History of sensitivity to *Melissa officinalis*, Olfactory sense disorder, History of respiratory allergy or asthma

Intervention groups

Intervention group: Routine treatment as well as aromatherapy with *Melissa officinalis* twice a day for three consecutive days
Control group: Routine treatment as well as aromatherapy with placebo prepared by sesame oil twice a day for three consecutive days

Main outcome variables

Primary outcome: Sleep quality
Blood pressure
Heart rate
Breathe rate
Arterial blood oxygen saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N304**

Registration date: **2019-09-30, 1398/07/08**

Registration timing: **retrospective**

Last update: **2019-09-30, 1398/07/08**

Update count: **0**

Registration date

2019-09-30, 1398/07/08

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics
Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-07-23, 1398/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of aromatherapy with *Melissa officinalis* versus

placebo on the sleep quality and physiological indicators in patients admitted at the cardiac care unit: a single-blind randomized clinical trial

Public title
Effect of aromatherapy with *Melissa officinalis* versus placebo on the sleep quality and physiological indicators in patients admitted at the cardiac care unit

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age of 18 to 65 years, Sleep disorder
Exclusion criteria:
History of sensitivity to *Melissa officinalis*, Olfactory sense disorder, History of respiratory allergy or asthma

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **98**

Randomization (investigator's opinion)
Randomized

Randomization description
Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.

Blinding (investigator's opinion)
Single blinded

Blinding description
The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. Thus, the trial will be run as triple blind

Placebo
Used

Assignment
Parallel

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
Vice-chancellor for Research and Technology, Shahid Beheshti University of Medical Sciences, Danshjou Bul.

City
Tehran

Province
Tehran

Postal code
1985717443

Approval date
2019-05-05, 1398/02/15

Ethics committee reference number
IR.SBMU.RETECH.REC.1398.057

Health conditions studied

1

Description of health condition studied
Sleep disorder

ICD-10 code
F51.8

ICD-10 code description
Other sleep disorders not due to a substance or known physiological condition

Primary outcomes

1

Description
Sleep quality

Timepoint
Before the intervention and 24, 48 and 72 hours after the intervention

Method of measurement
Using the Verran and Snyder-Halpern Sleep Scale

2

Description
Blood pressure

Timepoint
Before the intervention and 15, 30 and 60 minutes after the intervention

Method of measurement
Using a monitoring machine

3

Description
Heart rate

Timepoint
Before the intervention and 15, 30 and 60 minutes after the intervention

Method of measurement
Using a monitoring machine

4

Description

Breathe rate
Timepoint
Before the intervention and 15, 30 and 60 minutes after the intervention
Method of measurement
Using a monitoring machine

5

Description
Arterial blood oxygen saturation
Timepoint
Before the intervention and 15, 30 and 60 minutes after the intervention
Method of measurement
Using a monitoring machine

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Routine treatment as well as aromatherapy with Melissa officinalis for 2 hours twice a day for three consecutive days
Category
Treatment - Drugs

2

Description
Control group: Routine treatment as well as aromatherapy with placebo prepared by sesame oil for 2 hours twice a day for three consecutive days
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Rajaei Hospital in Tehran City
Full name of responsible person
Adeleh Lotfi
Street address
Shahid Rajaei, Niayesh intersection, Vali Asr Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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
Tehran University of Medical Sciences
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Adeleh Lotfi
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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

Undecided - It is not yet known if there will be a plan to make this available

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