Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effects of inhalator aromatherapy with Citrus Aurantium L. essence versus placebo on the sleep quality in heart patients: a single blinded randomized clinical trial

Protocol summary

Summary

Objective: The effects of aroma “Citrus aurantium” on sleep quality in heart patients. Design: Population: Heart patients hospitalized in coronary care units of Abu Ali Sīnā hospital in Qazvin. The Sample Size in Intervention and Control Groups is 30 people each. Method: First, the Informed Consent form for research should be signed. Then, the patients will be enter in study if they have score more than five in Epworth Sleepiness Scale and be positive according to the Berlin obstructive sleep apnea in idiopathic intracranial hypertension and finally, the Hospital Sleep Questionnaire will be completed before and after intervention. The Interventions: The sensitivity of the test with one drop of essence of Citrus aurantium with 2.5% concentration in the Intervention group, and the sunflower oil in the control one, and if no sensitive symptoms being caused during three successive nights, three drops of essence of Citrus aurantium with ten percent concentration at night will be taken via the nose by inhalation in the intervention group, and the patients will need to take three deep breaths too. In control group, three drops of the sunflower oil via the nose along with three deep breaths will be used. Main outcome variables: The patients’ sleep quality according to the Hospital Sleep Questionnaire “SMHSQ” will be measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013121415789N1**
Registration date: **2014-02-08, 1392/11/19**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-02-08, 1392/11/19

Registrant information

Name
Fariba Mohamadi hariry
Name of organization / entity
Qazvin University of medical science
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

The cost of personnel: 9500000 Rails- Cost Tools: 500,000 Rails- Total Cost: 10 million Rails

Expected recruitment start date

2014-01-21, 1392/11/01

Expected recruitment end date

2014-03-06, 1392/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of inhalator aromatherapy with Citrus Aurantium L. essence versus placebo on the sleep quality in heart patients: a single blinded randomized clinical trial

Public title

The effects of aroma " Citrus aurantium L." on sleep quality in heart 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 aged over 18 and under 65. Patients with no medical histories of mental illness having led to a long period hospitalization and the consumption of psychiatric drugs. No use of herbal medicines in the past two weeks. Having no allergic histories to medicines and all herbs (Herbal Medicines or Herbal remedies) No allergy symptoms were caused about all the medicines they had taken in the allergy tests. Positive indicators of Epworth Questionnaire (score>5) To have taken “Berlin questionnaire for sleep apnea” to be positive. Exclusion Criteria: Vital sign instability which leads to a change in drug instructions. Dosage change and the sedative drugs deletion, if desired. The transference of patients from the Cardiac Care Unit to the other wards. To be discharged from the hospital –doctor’s orders or against medical advice. To display no tendencies to cooperate on the research any longer. Allergy symptoms are to be caused.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
1
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
Used
Assignment
Parallel
Other design features
Randomization: in start of sampling, two blue and red balls (Called the Control and intervention balls come into use randomly selected from each of the cardiac care units (the two wards) just for the sake of sampling, and some alterations are being made to the sampling place alternatively every week until the size of the samples has reached 30. How to blind? No one knows in what groups they will be placed.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Qazvin University of Medical Sciences
Street address
Qazvin University of Medical Sciences, Shahid Bahonar Blvd, Qazvin
City
Qazvin
Postal code
3419759811
Approval date
2013-07-15, 1392/04/24
Ethics committee reference number
20/7615/ر

Health conditions studied

1

Description of health condition studied
Heart Disease
ICD-10 code
120-121-12
ICD-10 code description
Ischemic Heart Disease

Primary outcomes

1

Description
Sleep Quality
Timepoint
2 hours preintervention - 3 days post intervention
Method of measurement
St Marry's Hospital Sleep Questionnaire

Secondary outcomes

1

Description
Sensitivity to Citrus Aurantium L. essence
Timepoint
2 hours preintervention- every 3 hours during intervention and 2 hours post intervention
Method of measurement
Clinical signs and symptoms

Intervention groups

1

Description
Intervention group: Aroma "Citrus aurantium" was prepared by Research Institute of Forests and

Rangelands, Tehran, and diluted with sun flower oil to 10 percent of dilution. For three consecutive nights using the inhalation, every night is poured three drops on a tissue and inhale three deep breathes by patient. SMHSQ before and after will be completed.

Category

Treatment - Other

2

Description

Control group: Pure sun flower oil, for three consecutive nights using the inhalation, every night is poured three drops on a tissue and inhale three deep breath by patient. SMHSQ before and after will be completed.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Bu Ali Sina Hospital

Full name of responsible person

Fariba Moahmadi Hariry

Street address

Qazvin University of Medical Science, Shahid Bahonar Blvd. Qazvin

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Qazvin University of Medical Sciences

Full name of responsible person

Zinat jourabchi

Street address

Qazvin University of Medical science - Shahid Bahonar Blvd. Qazvin

City

Qazvin

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, Qazvin 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

Qazvin University of Medical Science

Full name of responsible person

Fariba Mohamadi Hariry

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