

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 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 Sina 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 26 3661 6793

###### Email address

aghoudosi@qums.ac.ir

##### 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

20/7615/3

## Health conditions studied

### 1

#### Description of health condition studied

Heart Disease

#### ICD-10 code

I20-I21-I22

#### 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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**Person responsible for updating data**

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**Full name of responsible person**

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**Web page address**

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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*