

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

Effect of citrus Aurantium on sleep quality in the elderly with heart failure

Protocol summary

Summary

Objectives: The aim of this study was to determine the effect of citrus Aurantium on the quality of sleep in elderly patients with heart failure. Design: this non blinding randomized clinical trial is done in the heart and CCU parts of Fatemeh Zahra Hospital in Sari, Razi Hospital in Ghaemshahr, Rouhani in Babol. Study Population : Elderly patients with heart failure. Inclusion criteria: Age 60 and above, NYHA class 3 and 4, Passed at least 24 hours of admission and stabilization of clinical signs, no history of allergy to citrus Aurantium. The absence of illnesses affecting the sense of smell, the lack of use of herbal remedies affecting sleep over the past two weeks. Exclusion criteria: Signs of severe allergy to citrus Aurantium, no drug and smoking, no consumption antidepressants, sedative and antihistamines, no cooperation, Lowering the level of consciousness and cardiac arrest during the study, get out of the study environment for more than 30 minutes per night. Sample size: 80 patients are divided into two groups: control and intervention. Intervention: At first, demographic characteristics questionnaire and hospital sleep quality questionnaire were completed in both groups. 128/5000 In the intervention group, two drops of essential oil of 10% citrus Aurantium, placed on a cotton ball and placed within a distance of ten centimeters from the patient's nose. The patient is taught to stay on the pillow for twenty minutes. Patients in the control group receive routine care. After three nights, after a refreshing treatment, the hospital sleep quality questionnaire is filled.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017061134454N1**

Registration date: **2017-06-30, 1396/04/09**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-06-30, 1396/04/09

Registrant information

Name

Ehteram Sadat Ilali

Name of organization / entity

Mazandaran University of Medical Sciences

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Iran (Islamic Republic of)

Phone

+98 11 3336 7342

Email address

z.arab1388@gmail.com

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2017-07-21, 1396/04/30

Expected recruitment end date

2017-09-21, 1396/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of citrus Aurantium on sleep quality in the elderly with heart failure

Public title

Sleep quality in heart failure

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Age 60 and above, NYHA class 3 and 4, Passed at least 24 hours of admission and stabilization of clinical signs, no history of allergy to citrus Aurantium. The absence of illnesses affecting the sense of smell, the lack of use of herbal remedies affecting sleep over the past two weeks. Exclusion criteria: Signs of severe allergy to citrus Aurantium, no drug and smoking, no consumption antidepressants, sedative and antihistamines, no cooperation, Lowering the level of consciousness and cardiac arrest during the study, get out of the study environment for more than 30 minutes per night.

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Clinical randomized blocked clinical trials

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mazandaran University of Medical Sciences

Street address

Mazandaran University of Medical Sciences (Vice chancellor for research), Moallem Square.

City

Sari

Postal code

4816715793

Approval date

2017-06-10, 1396/03/20

Ethics committee reference number

IR.MAZUMS.REC.96.3064

Health conditions studied

1

Description of health condition studied

Sleep Quality

ICD-10 code

G47

ICD-10 code description

Sleep Disorders

Primary outcomes

1

Description

Sleep Quality

Timepoint

Before the intervention, on the morning of the fourth day after three nights the healing aroma

Method of measurement

Hospital Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The patients of control group will receive the usual care.

Category

Other

2

Description

At the beginning of the study, questionnaires (demographic characteristics questionnaire and hospital sleep quality questionnaire) were completed in both groups. In the intervention group, two drops of 10% orange spring essential oil are placed on a cotton ball and placed within a distance of ten centimeters from the nose of the patient and the patient is trained to keep the patch on for 20 minutes. After the end of three nights, the healthcare scent is filled in with the researcher on the morning of the fourth day after waking up and announcing the readiness.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemeh Zahra Hospital, Sari

Full name of responsible person

Zulikha Arab Firoozjany

Street address

Fatemeh Zahra Hospital, Military Boulevard, Municipality

Square
City
Sari

empty

Person responsible for general inquiries

2

Recruitment center

Name of recruitment center
Razi Hospital ,Ghaemshahr
Full name of responsible person
Zulikha Arab Firoozjary
Street address
Ghaemshahr, Yousef Reza St., Razi Hospital
City
Ghaemshahr

3

Recruitment center

Name of recruitment center
Rouhani Hospital,Babol
Full name of responsible person
Zulikha Arab Firoozjary
Street address
Babol, University Square, Ganj Afrouz Street, Rouhani Hospital
City
Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research,Mazandaran University of Medical Siences
Full name of responsible person
Ahmad Ali Enayati
Street address
Mazandaran University of Medical Sciences(Vice chancellor for research),Moallem Square.
City
Sari

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,Mazandaran University of Medical Siences

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

Contact

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Zulikha Arab Firoozjary
Position
Master Student in Old age nursing
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Person responsible for scientific inquiries

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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