Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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Ehteram Sadat Ilali
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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 Siences(Vice chanchellor 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 Firoozjayy

Street address
Fatemeh Zahra Hospital,Military Boulvard,Municipality

Square
City
Sari

2

Recruitment center
Name of recruitment center
Razi Hospital ,Ghaemshahr
Full name of responsible person
Zulikha Arab Firoozjayy
Street address
Ghaemshahr, Yousef Reza St., Razi Hospital
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3

Recruitment center
Name of recruitment center
Rouhani Hospital,Babol
Full name of responsible person
Zulikha Arab Firoozjayy
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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
empty

Person responsible for general inquiries

Contact
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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