Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

The effect of matricaria recutita drop on sleep quality in patients with choronic heart failure hospitialized

Protocol summary

Study aim
The effect of matricaria recutitaon on sleep quality in patients with choronic heart failure

Design
A randomized, triple stage, triple blinded and two-group clinical trial

Settings and conduct
This study is done in Shahid Chamran Hospital in Isfahan. The target group are patients who referred to the center for the treatment of chronic heart failure, and are suffering from at least one sleep disorder. After administering matricaria recutita to the intervention group and placebo for the control group, the patients' sleep quality was assessed by the St. Mary's Hospital Sleep Quality Questionnaire in three stages. The study is triple blind and this is done by two collaborators in the implementation of the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 40 to 67 years old; Mild to moderate heart failure; Different degrees of sleep disorders; Not having a physical illness affecting sleep; Do not use drugs that affect sleep Non-inclusion criteria: History of myocardial infarction in the last three months; significant arrhythmia

Intervention groups
Intervention group 1: Patients take 2 ml of products containing chamomile at a specified hour for one week. Group 2: Group medication. Patients in this group use the placebo as same as the amount of intervention group 1 at the same time for one week.

Main outcome variables
Patients' sleep quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171216037895N2**
Registration date: **2019-05-18, 1398/02/28**
Registration timing: **retrospective**

Last update: **2019-05-18, 1398/02/28**
Update count: **0**

Registration date
2019-05-18, 1398/02/28

Registrant information

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Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-07-23, 1397/05/01

Expected recruitment end date
2018-09-22, 1397/06/31

Actual recruitment start date
2018-07-23, 1397/05/01

Actual recruitment end date
2018-09-22, 1397/06/31

Trial completion date
2018-09-22, 1397/06/31

Scientific title
The effect of matricaria recutita drop on sleep quality in patients with choronic heart failure hospitialized

Public title
The effect of matricaria recutita on the quality of sleep

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Being aware of time and place The absence of neurological and psychiatric diseases mentioned in the medical history of the patient Age 40 to 67 years old Familiar with Farsi Mild to moderate heart failure Ejection fraction between 20 to 40% Different degrees of sleep disorders include insomnia, delayed sleep, sleep deprivation, sleep disturbance, and overall sleep quality score of over 12, based on St. Mary's Hospital Sleep Quality Questionnaire Not having a physical illness affecting sleep, such as asthma and thyroid disorders Do not use drugs that affect sleep such as sedation, housing, antidepressants No smoking and alcohol Not having any sensitivity to chamomile and its compounds by means of a questionnaire through a demographic questionnaire on the absence of nausea and vomiting and skin rash following the use of its compounds Not having sleep apnea Failure to develop restless leg syndrome Lack of severe pain and sleep discomfort Not using complementary medicine in a recent week Stability of vital signs

Exclusion criteria:

History of heart attack three months ago Significant arrhythmia

Age

From **40 years** old to **67 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

Actual sample size reached: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Peoples who have inclusion criteria will be randomly assigned into two groups of intervention and control. In this way, 35 cards with number one and 35 cards with number two are enclosed in an envelope, and they are asked to select a card on the day of the random division of the research units. People with number are located in test group, and those with number two are included in control group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

To eliminate individual factors in the results, the study is done as triple blind. Thus, the samples do not know in which group they are located. Furthermore, two collaborators are hired to do the sampling. In this way, collaborators provide the samples with the medicine and questionnaire. The statistician is not aware of the treatment groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences., Street Hezarjarib

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2018-07-15, 1397/04/24

Ethics committee reference number

IR.MUI.RESEARCH.REC.1397.039

Health conditions studied

1

Description of health condition studied

Sleep disorders

ICD-10 code

G47

ICD-10 code description

Sleep disorders

2

Description of health condition studied

Chronic heart failure

ICD-10 code

I50

ICD-10 code description

Heart failure

Primary outcomes

1

Description

Sleep quality

Timepoint

Before the intervention, three days and a week after the

intervention

Method of measurement

St. Mary's Hospital Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention receives chamomile drops, called chamazulene (containing a complete extract of chamomile), at 30 drops (about 2 cc), manufactured by Sina Farouor Pharmaceutical Company in Isfahan, in half a glass of water plus half a cube of sugar under the supervision of a doctor before bedtime at midnight in the cardiology department of the hospital for one week.

Category

Treatment - Drugs

2

Description

Control group: In this group, patients are followed up for one week by a doctor. In the same way as a test group, they receive a placebo or a prescriber at the same hour before bedtime. The placebo contains 1.0 cc of the main medicine. This means that there is 1 cc of the main medicine in 10 cc of hydrochemical solution. Moreover, the placebo in terms of color, odor, appearance, and packaging is not different from the original medicine. However, it can be distinguished from the original medicine by the code.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Shahid Chamran Hospital

Full name of responsible person

Mohammadreza Shafiei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Shahram Rashidi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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