Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

The effect of Melissa officinalis on sleep quality and anxiety in patients who suffer from acute coronary syndrome

Protocol summary

Summary

Objective: Determination of the effect of Melissa Officinalis on sleep quality and anxiety in patients who suffer from acute coronary syndrome -Design: randomized double-blind, placebo-controlled trial - Inclusion criteria: patients (male, female) with acute coronary syndrome; age 30 to 80 years old; Patient's willingness to participate in the study; being fully alert and able to communicate; having no history of sleep disturbance before admission; having no history of chronic pain; alcoholism; drug use; COPD and sleep apnea. -Exclusion criteria: not willing to continue co-operation with the study; death -Sample size: 72 - Intervention: Case group receives 2 grams Melissa Officinalis (4 capsules contains 500 mg Melissa Officinalis daily) for 7 days and control group receives 2 grams starch powder daily (4 capsules contains 500 mg starch powder daily) for 7 days. - Outcomes: Melissa Officinalis is expected to improve the quality of sleep and anxiety of patients with acute coronary syndrome in the CCU.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017070234851N1**
Registration date: **2017-08-21, 1396/05/30**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-08-21, 1396/05/30

Registrant information

Name

Maryam Emami

Name of organization / entity

Faculty of Nursing and Midwifery Shahed

Country

Iran (Islamic Republic of)

Phone

+98 21 6641 8587

Email address

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Recruitment status

Recruitment complete

Funding source

Shahed University

Expected recruitment start date

2017-08-11, 1396/05/20

Expected recruitment end date

2018-01-20, 1396/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Melissa officinalis on sleep quality and anxiety in patients who suffer from acute coronary syndrome

Public title

Melissa Officinalis effect on sleep quality and anxiety in patients with acute coronary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Entry criteria: company in the study; patients tend to benefit from mental health; not having the experience of sleep disorder before bed; having full consciousness and able to communicate; having no history of chronic pain; addiction to alcohol and drugs; having at least 30 years of age up to 80; the first patient to be hospitalized; the ability to turn taking medication orally; the history of

Sleep apnea and COPD; while according to the rating criteria for differentiating diagnosis of Pittsburgh sleep disorder questionnaire before bed with sleep disturbances caused by the patient's hospitalization if you get 0-4 points will be studied; the history of PCI. Exit criteria: cancel the patient's continued cooperation; the patient's feet

Age
From **30 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shahed University

Street address
Shahed University، In front of Imam Khomeini(ra)'s holy shrine، First of Tehran_Qom free way

City
Tehran

Postal code
3319118651

Approval date
2017-07-19, 1396/04/28

Ethics committee reference number
IR.Shahed.REC.1396.21

Health conditions studied

1

Description of health condition studied
Acute coronary syndrome

ICD-10 code
I24.9

ICD-10 code description
Acute ischaemic heart disease, unspecified

Primary outcomes

1

Description
Sleep quality

Timepoint
before intervention- at the end of intervention

Method of measurement
Richards-Campbell Sleep Questionnaire (RCSQ)

2

Description
Anxiety

Timepoint
before intervention- at the end of intervention

Method of measurement
Spielberger State-Trait Anxiety Inventory (STAI)

Secondary outcomes

1

Description
The side effects of medication

Timepoint
before intervention- at the end of intervention

Method of measurement
Side effects form of medication

Intervention groups

1

Description
Case group receives 2 grams Melissa Officinalis (4 capsules contains 500 mg Melissa Officinalis daily) for 7 days

Category
Treatment - Drugs

2

Description
control group receives 2 grams starch powder daily (4 capsules contains 500 mg starch powder daily) for 7 days

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Hospital of Valiasr Qom، CCU

Full name of responsible person

Maryam Emami، MSc Student of critical care Nursing

Street address

Islamic Republic Blvd، Amin Blvd، Qom

City

Qom

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Dr.Zahra Kiasalar(Vice President of Research)

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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

Shahed University

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

Faculty of Nursing and Midwifery Shahed

Full name of responsible person

Maryam Emami

Position

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Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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Name of organization / entity

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Web page address

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