Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Melisa Offcinalis on sleep quality, anxiety and depression in patients after coronary artery bypass surgery

Protocol summary

Summary

The purpose of this study was to evaluate the effect of Melissa officinalis on improving sleep disturbance, anxiety and depression in patients after open heart surgery.Inclusion criteria: age of 30 to 70 years, lack of sleep disorders in recent months, according to a questionnaire Pittsburgh, lack of mental disorder according to criteria Khrvch Rprvanpzshk advice: stay more than 5 days in open heart surgery, the patient withdrew from further cooperation, the return of the patient to the operating room, the patient died.The number of patients participating in this study, 80 patients who have open-heart surgery in Hazrat Vali-e Qom.Patients were recruited from 1 to 80 canisters have accidentally received coding. Anxiety and sleep quality before and after taking the case study on a seven-day, three times a day, re-checked. .Sleep quality and to check for SMHSQ questionnaire HADS anxiety and depression questionnaire used

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014071918531N1**
Registration date: **2015-01-29, 1393/11/09**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-01-29, 1393/11/09

Registrant information

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Name of organization / entity
Shahed University
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Shahed University

Expected recruitment start date

2014-06-05, 1393/03/15

Expected recruitment end date

2014-11-06, 1393/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Melisa Offcinalis on sleep quality, anxiety and depression in patients after coronary artery bypass surgery

Public title

Effect of Melisa Offcinalis on reducing depression and anxiety and improve sleep quality in patients after open heart surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The minimum age of 30 years and maximum 70 years؛Lack of sleep disorders, at least in recent months, according to a questionnaire Pittsburgh ؛Lack of mental disorder by a psychiatrist Exclusion criteria:hospitalized for more than 5 days in open heart surgery؛The patient withdrew cooperation؛The return of the patient to the operating room؛The patient died

Age
From **63 years** old to **23 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Triple 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
Beginning Highway Tehran - Qom. In front of the shrine of Imam Khomeini
City
tehran
Postal code
3319118651
Approval date
2014-05-26, 1393/03/05
Ethics committee reference number
201822/41

Health conditions studied

1

Description of health condition studied
Impaired sleep quality, anxiety and depression after open heart surgery
ICD-10 code
I97.1
ICD-10 code description
Other functional disturbances following cardiac surgery

Primary outcomes

1

Description
Quality of sleep
Timepoint
Before and one week after the intervention
Method of measurement
Questionnaire SMHSQ

2

Description
Preoperative anxiety
Timepoint
Preoperative
Method of measurement
Amsterdam Preoperative Anxiety Scale

3

Description
Hospital Anxiety
Timepoint
before began the intervention and A week after intervention
Method of measurement
HADS Hospital Anxiety and Depression Scale

4

Description
Depression hospital
Timepoint
before began the intervention and a week after intervention
Method of measurement
HADS Hospital Anxiety and Depression Scale

Secondary outcomes

empty

Intervention groups

1

Description
Capsules 500 mg orally three times daily for the intervention group lemon balm for 7 days
Category
Treatment - Drugs

2

Description
Starch capsules 500 mg orally three times to control particle day for 7 days
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr Hospital
Full name of responsible person
Alireza Soltanpour
Street address
Qom - Boulevard of the Islamic Republic
City
Qom

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahed University
Full name of responsible person
Dr. Mohammad Reza Hiedari
Street address
Beginning of Tehran to Qom. Imam Khomeini's shrine
City
Tehran
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
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Person responsible for scientific inquiries

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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