

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 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

Name

Ali Reza Soltanpour

Name of organization / entity

Shahed University

Country

Iran (Islamic Republic of)

Phone

+98 21 6641 8592

Email address

a.soltanpour@shahed.ac.ir

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

Name of organization / entity

Shahed University

Full name of responsible person

Alireza Soltanpour

Position

Critical Care Nursing Graduate Student

Other areas of specialty/work

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Contact

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Shahed University

Full name of responsible person

Dr. Mohammad Reza Heidari

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phd of nursing

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soltanpour@shahed.ac.ir

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