

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of effects of Oxazepam, Valeriana officinalis, Lavandula angustifolia Mill and placebo on anxiety and sleep quality in patients with coronary artery disease

Protocol summary

Summary

(1) This study aims to compare the effects of Oxazepam, Valeriana officinalis, Lavandula angustifolia and placebo on anxiety and sleep quality of patients with coronary artery disease admitted to the cardiac ward of Birjand Vali-Asr Hospital. (2) This clinical trial is in the second phase and is double-blind as the researcher who collects data and the patients will not be aware of the type of treatment. There are four 30-member groups including lavender (5cc essential oil manufactured by Zardband pharmaceutical company), valerian (5 cc extracts manufactured by Zardband pharmaceutical company), Oxazepam (10 milligram tablets) and placebo (5 cc water). (3) Participants will include a total of 120 patients with coronary artery disease who will be selected by random sampling. They should be aged between 30-70 years and have no history of mental illness or sensitivity to valerian and lavender. They should provide informed consent and can withdraw from participation in case they intend. (4) The participants will be recruited in Vali Asr Hospital of Birjand and allocated into study groups through simple randomization method. (5) Lavender essence, valerian essence, and placebo will be given to members of the related groups 5 milliliters a night for three successive nights. Similarly, one 10 mg Oxazepam tablet dissolved in 5 ml of distilled water will be given to patients in the Oxazepam group for three successive nights. (6) Data on state and trait anxiety and sleep quality will be collected before intervention and 3 days after intervention in the 4 group using Spielberger's State and Trait Anxiety Inventory and Pittsburgh Sleep Quality Index.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016091429822N1**

Registration date: **2016-12-31, 1395/10/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-12-31, 1395/10/11

Registrant information

Name

Marzie Rafie Bigan

Name of organization / entity

Birjand University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellery for Research and Technology of Birjand University of Medical Sciences

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2016-12-30, 1395/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effects of Oxazepam, Valeriana officinalis, Lavandula angustifolia Mill and placebo on anxiety and sleep quality in patients with coronary artery disease

Public title

Effects of Oxazepam, valerian, lavender and placebo on anxiety and sleep quality in patients with coronary artery disease

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age between 30 to 70 years; willingness to participate in the study; no risk of heart failure (class III and IV) and cardiogenic shock; no use of complementary alternative medicine methods (herbal medicines and other methods) during the two weeks preceding intervention; no use of sleeping drugs, benzodiazepines, and sedative drugs; no addiction; no history of allergy to flowers, plants, valerian and lavender; no history of mental illness; stable vital signs; gaining a score of above 20 on the Spielberger's State and Trait Anxiety Inventory; obtaining a score equal to or over 5 on the Pittsburgh's Sleep Quality Index. Exclusion criteria: No cooperation during the study; sudden changes in the patient's hemodynamic status

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **120**

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

Ethics Committee of Birjand University of Medical Sciences

Street address

Birjand University of Medical Sciences, Ghaffari st.,

City

Birjand,

Postal code

Approval date

2016-10-16, 1395/07/25

Ethics committee reference number

lr.bums.REC.1395.104

Health conditions studied

1

Description of health condition studied

Coronary Artery Disease

ICD-10 code

I25.1

ICD-10 code description

Coronary Artery Disease

Primary outcomes

1

Description

sleep quality

Timepoint

before intervention and 3 days after intervention

Method of measurement

Pittsburgh Sleep Quality Index

2

Description

State and trait anxiety

Timepoint

before intervention and 3 days after intervention

Method of measurement

Spielberger's State and Trait Anxiety Inventory

Secondary outcomes

empty

Intervention groups

1

Description

Lavender intervention group: 5 cc essential oil, every night for 3 nights

Category

Treatment - Drugs

2

Description

Valerin intervention group: 5 cc extract of valerian, every night for 3 nights

Category

Treatment - Drugs

3

Description

Placebo group: 5 cc water, every night for 3 nights

Category

Placebo

4

Description

Oxazepam intervention group: one 10 mg oxazepam dissolved in 5 ml of distilled water, every night for 3 nights

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali Asr Hospital of Birjand

Full name of responsible person

Marzie Rafie Bigan

Street address

Ghafari Street,

City

Birjand,

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellery for Research and Technology of
Birjand University of Medical Sciences

Full name of responsible person

Gholamreza Sharifzadeh

Street address

Birjand University of Medical Sciences, Ghafari Street,

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Birjand,

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice-Chancellery for Research and Technology of Birjand
University of Medical Sciences

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

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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