Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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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
Ir.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,
City
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

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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