

# 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

Iran (Islamic Republic of)

###### Phone

+98 56332395000

###### Email address

m.rafee@bums.ac.ir

##### 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,

##### 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

#### Contact

##### Name of organization / entity

Birjand University of Medical Sciences

##### Full name of responsible person

Marzie Rafie Bigan

##### Position

Master's Student

##### Other areas of specialty/work

##### Street address

Ghafari Street,

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## Person responsible for updating data

#### Contact

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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*