Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of Rosa damascene extract on anxiety rate and sleep quality candidate angiography:A double-blind randomized controlled trial

Protocol summary

Summary

The aim of this study was the effect of Rose damascenes extracts on anxiety rate and sleep quality. In this randomized clinical trial, 90 patients were randomly allocated to two groups: intervention and control group (45 patients in each group).The study will be conducted on cardiac patients hospitalized in CCU of Rajaee hospital in Karaj. In both groups at the first day of admonition, Sent merry sleep questioner and Espiel berger questioner for anxiety will be completed then in intervention group 24 hours before angiography(every 8 hours,15drop Rose damascene extract) and in control group 24 hours before angiography (every 8 hours,15drop placebo)will be given. In the morning of angiography day in both groups, both questioners will be completed. This clinical trial is double blind and scholar and patient are unaware about drops contents.

General information

Acronym

IRCT registration number

IRCT registration information

IRCT registration number: **IRCT2015112425221N1**
Registration date: **2016-02-02, 1394/11/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-02-02, 1394/11/13

Registrant information

Name

soodabeh Babaee

Name of organization / entity

school of nursing and midwifery Ardabil

Country

Iran (Islamic Republic of)

Phone

+98 45 3372 6085

Email address

so.babaee@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ardebil University of Medical Sciences

Expected recruitment start date

2015-11-22, 1394/09/01

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Rosa damascene extract on anxiety rate and sleep quality candidate angiography:A double-blind randomized controlled trial

Public title

The effect of Rosa damascene extract on anxiety rate and sleep quality, candidate angiography

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion / Exclusion: Inclusion criteria: age above 18 years with cardiac disease, candidate angiography, absence of angiography history and in their family, literacy, signing the informed consent sheet, absence of anxiety and sleep disorders, alert patients, at least 24, hours hospitalization .Exclusion criteria: Asthma and allergy history, using complementary medicine in recent week, using sedative and hypnotic medicine, critical ill and cancellation of work.

Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
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 Ardabil University
Street address
Ardabil,medical science university,Pardis office ,university square,end of university avenue
City
Ardabil
Postal code
5618985991
Approval date
2015-10-04, 1394/07/12
Ethics committee reference number
IR.ARUMS.REC.1394046

Health conditions studied

1

Description of health condition studied
anxiety
ICD-10 code
F41.9
ICD-10 code description
anxiety NOS

2

Description of health condition studied
sleep quality
ICD-10 code
F51
ICD-10 code description
Nonorganic sleep disorders

Primary outcomes

1

Description
Anxiety
Timepoint
Before and after intervention,before angiogeraphy
Method of measurement
Eshpilberger questioner

2

Description
sleep quality
Timepoint
The night before and after intervention
Method of measurement
sent merrys hospital sleep questioner

Secondary outcomes

empty

Intervention groups

1

Description
In intervention group, Damascene Rose extract in oral drop, Construction Barij Essence Pharmaceutical Company(every 8 hours,15 drop with a little of water will be given.
Category
Treatment - Drugs

2

Description
In control group, placebo in oral drop form, every 8 hours, 15drop with a little of water will be given. Placebo is similar to extract and it is made by Barij Essence Pharmaceutical Company.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Rajaee educational Hospital Alborz university of medical science karaj. Iran
Full name of responsible person
soodabeh Babaee
Street address
Karaj,Shahid Rajaee Hospital,Shahid Beheshti avenue
City

Karaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil medical university,Vice chancellor for research

Full name of responsible person

Dr,shahram Habib zadeh

Street address

Ardabil, medical science university,Pardis office, university square, end of university avenue Ardabil

City

Ardabil

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ardabil medical university,Vice chancellor for research

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

School of nursing and midwifery Ardabil

Full name of responsible person

soodabeh Babaee

Position

Nursing master student

Other areas of specialty/work

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Zahra Tazakori

Position

Assistance professor

Other areas of specialty/work

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Person responsible for updating data

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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