

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effects of the herb of valerian oil (*valeriana officinalis*) and lavender (*lavandula angustifolia* MILL) with diazepam on preoperative anxiety in patients between 48-14 years old

Protocol summary

Summary

This study aimed to compare the effects of two drugs of *valeriana officinalis* and *lavandula angustifolia* essential oil with diazepam on preoperative anxiety in hospitalized patients in Kashani hospital. In this double blind clinical trial, 120 patients undergoing moderate elective surgery, the average age range of 14- 48 years with no history of previous surgery, mental illness and sensitivity to valerian and lavender were recruited by convenience sampling method. Patients were randomly divided into four groups of 30 recipients of lavender (5cc edible oil manufactured by Zardband pharmaceutical company), valerian (5 cc concentrated extracts manufactured by theZardband pharmaceutical company), diazepam (tablets 5mg) and placebo, respectively. The person who Completed the questionnaire, the patients and researchers were not aware of the type of treatment. The individual state anxietyscore before and 2 hours after drug administration through STAI questionnaire was calculated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014121018099N2**

Registration date: **2015-10-10, 1394/07/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-10-10, 1394/07/18

Registrant information

Name

Gholamreza Shabaniyan

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Shahrekord University of Medical sciences

Expected recruitment start date

2013-01-01, 1391/10/12

Expected recruitment end date

2014-04-01, 1393/01/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of the herb of valerian oil (*valeriana officinalis*) and lavender (*lavandula angustifolia* MILL) with diazepam on preoperative anxiety in patients between 48-14 years old

Public title

Effects of two herbal medicine of *valeriana officinalis* and *lavandula angustifolia* MILL on preoperative anxiety

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients between the age of 14- 48 years old referring to Ayatollah Kashani hospital, Shahrekord, Iran; patients undergoing moderate elective

surgery; patient satisfaction to participate in the study.
Exclusion criteria: patients with a history of mental illness, previous surgery; patients sensitive to valeriana officinalis, lavandula angustifolia or both.

Age

From **14 years** old to **48 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

Shahrekord University of Medical Sciences

Street address

Shahrekord University of Medical Sciences, Kashani Blvd, Shahrekord

City

Sharekord

Postal code

Approval date

2013-01-01, 1391/10/12

Ethics committee reference number

1171

Health conditions studied

1

Description of health condition studied

Anxiety before the surgery

ICD-10 code

F40

ICD-10 code description

Phobic anxiety disorders

2

Description of health condition studied

Ective surgery

ICD-10 code

Y83.8

ICD-10 code description

Other surgical procedures

Primary outcomes

1

Description

Anxiety before the surgery

Timepoint

Before and 2 hours after prescription of drug

Method of measurement

Anxiety (STAI) Questionnaire

Secondary outcomes

1

Description

Vital signs (blood pressure, pulse and respiration)

Timepoint

Before and 2 hours after prescription of drug

Method of measurement

Monitoring devices

2

Description

Vital signs (blood pressure, pulse and respiration)

Timepoint

Before and 2 hours after drug administration

Method of measurement

Monitoring devices

Intervention groups

1

Description

Edible oil of lavender, 5 ml single dose

Category

Treatment - Drugs

2

Description

Diazepam tablets, 5 mg single dose

Category

Treatment - Drugs

3

Description

Placebo: single dose

Category

Placebo

4

Description

Edible oil symbol of valerian, 5 ml single dose

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Kashani Hospital

Full name of responsible person

Dr. Gholamreza Shabanian

Street address

Surgery Department, Ayatollah Kashani Hospital

City

Shahrekord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology,
Shahrekord University of Medical Sciences

Full name of responsible person

Dr. Mahmoud Mobasheri

Street address

Shahrekord University of Medical Sciences, Kashani
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City

Shahrekord

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research and Technology,
Shahrekord 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

Shahrekord University of Medical Sciences

Full name of responsible person

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Other areas of specialty/work

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Web page address

empty

Sharing plan

Informed Consent Form

empty

Deidentified Individual Participant Data Set (IPD)

Clinical Study Report

empty

empty

Study Protocol

Analytic Code

empty

empty

Statistical Analysis Plan

Data Dictionary

empty