Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Shabanian

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 38 3333 0061

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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 MILLon preoperative anxiety

Purpose

Treatment

Inclusion/Exclusion criteria

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

surgery; patient satisfactionto prticipate 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
Anexity before the surgry

Timepoint
Before and 2 hours after prescription of drug

Method of measurement
Anxiety (STAI) Questionaire

Secondary outcomes

1

Description
Vital signs (blood pressure, pulse and respiration)

Timepoint
Before and 2 hours after prescribtion 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 Blvd.
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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

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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