

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of valerian on sleep quality, anxiety and depression in hemodialysis' patients

Protocol summary

Summary

Objective: To determine the effect of valerian on sleep quality, anxiety and depression in hemodialysis' patients. Inclusion criteria: Over 18 years of age; hemodialysis 3 times a week for 3 hours; for more than 3 months; full consciousness; hearing and speech ability; and not having sensitivity to plants. Exclusion criteria: Physical or mental disability; drug abuse; cancer; hearing or visual disorder; experienced recent stressful event; kidney transplant; acute illness; body mass index over 30; liver disease; hepatitis; cirrhosis; travel; or death of the patient. Population under Study: Hemodialysis' patients of Kowsar in Semnan, 15 Khordad in Mahdishahr and Emam in Garmsar hospitals. Sample size: A pilot study including 30 patients, would determine the size of samples. First intervention: Group A use Valerian capsules (Sedamin 530 mg, Goldaru Co.) 60 minutes before bedtime for one month. After one month cleaning, group A will receive placebo. Participants complete questionnaires of quality of sleep, anxiety and depression before and after each intervention. Second intervention: Group B uses placebo capsules (starch 50 mg, Goldaru Co.) 60 minutes before bedtime for one month. After one month cleaning, group B will receive Valerian capsules (Sedamin 530 mg, Goldaru Co.). Participants complete questionnaires of quality of sleep, anxiety and depression before and after each intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201601286318N5**

Registration date: **2016-02-04, 1394/11/15**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-02-04, 1394/11/15

Registrant information

Name

Monir Nobahar

Name of organization / entity

Semnan University of Medical Sciences

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Iran (Islamic Republic of)

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Email address

Nobahar43@Yahoo.com

Recruitment status

Recruitment complete

Funding source

Semnan University of Medical Sciences

Expected recruitment start date

2016-02-13, 1394/11/24

Expected recruitment end date

2016-07-14, 1395/04/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of valerian on sleep quality, anxiety and depression in hemodialysis' patients

Public title

The effect of valerian on sleep quality, anxiety and depression in hemodialysis' patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Over 18 years of age; hemodialysis 3 times a week for 3 hours; for more than 3 months; full consciousness; hearing and speech ability; and not having sensitivity to plants. Exclusion criteria: Physical or mental disability; drug abuse; cancer; hearing or visual disorder; experienced recent stressful event; kidney transplant; acute illness; body mass index over 30; liver disease; hepatitis; cirrhosis; travel; or death of the patient.

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Semnan University of Medical Sciences

Street address

Nursing and Paramedical Faculty, University of Medical Sciences, Semnan

City

Semnan

Postal code

3513138111

Approval date

2016-01-18, 1394/10/28

Ethics committee reference number

IR.SEMUMSREC1394.145

Health conditions studied**1****Description of health condition studied**

Hemodialysis patients

ICD-10 code

F02.8

ICD-10 code description

Dementia in other specified diseases classified elsewhere

Primary outcomes**1****Description**

Sleep quality

Timepoint

Before the intervention, one month after the first intervention, one month after the cleansing and one month after the second intervention.

Method of measurement

In this study, sleep quality is measured by using Pittsburgh Sleep Quality Index. This measurement is performed within three consecutive months (before the intervention, one month after the first intervention, one month after the cleansing and one month after the second intervention). Scores above 5 indicates that a person has trouble in sleeping. Information for each person will be recorded in a specific questionnaire for each patient.

2**Description**

Situational anxiety

Timepoint

Before the intervention, one month after the first intervention, one month after the cleansing and one month after the second intervention.

Method of measurement

The state of anxiety is measured by using anxiety STAI questionnaire. In response to the scale of anxiety, the participants expressed their feelings at that moment. This measurement is performed within three consecutive months (before the intervention, one month after the first intervention, one month after the cleansing and one month after the second intervention). This is a self-report questionnaire to assess anxiety, which has twenty 4 choice questions, which is scored by Likert scoring scale. The scale scores ranges from 20 to 80. Based on the score obtained, each person is placed in one of the 3 anxiety groups of mild (20-39), moderate (40-59) or severe (60-80). Information for each person will be recorded in a specific questionnaire for each patient.

3**Description**

Depression

Timepoint

Before the intervention, one month after the first intervention, one month after the cleansing and one month after the second intervention.

Method of measurement

Depression is measured by using Beck Depression Inventory. Beck Depression Inventory tests their polls. This measurement is performed within three consecutive months (before the intervention, one month after the

first intervention, one month after the cleansing and one month after the second intervention). There are a total of 21 tests of four-point scale from zero to three to respond. Scores range from zero to 63. Score and severity of depression is divided to mild (11-16), moderate (17-29) and major (30-63). Information for each person will be recorded in a specific questionnaire for each patient.

Secondary outcomes

empty

Intervention groups

1

Description

Group A use Valerian capsules (Sedamin 530 mg, Goldaru Co.) 60 minutes before bedtime for one month. After one month cleaning, group A will receive placebo. Participants complete questionnaires of quality of sleep, anxiety and depression before and after each intervention.

Category

N/A

2

Description

Group B uses placebo capsules (starch 50 mg, Goldaru Co.) 60 minutes before bedtime for one month. After one month cleaning, group B will receive Valerian capsules (Sedamin 530 mg, Goldaru Co.). Participants complete questionnaires of quality of sleep, anxiety and depression before and after each intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar in Semnan, Khordad The 15th in Mahdishahr and Imam in Garmsar

Full name of responsible person

Monir Nobahar

Street address

Faculty Nursing and Paramedical, Semnan University of Medical Sciences, Semnan

City

Semnan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr. Ali Rashidypour

Street address

Semnan University of Medical Sciences, Boulvar Basij, Semnan

City

Semnan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

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Position

Assistant Professor of Semnan University of Medical Sciences

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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