

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jan 2020

### 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 3365 4190

##### Email address

nobahar43@sem-ums.ac.ir

##### 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 Emam 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

Monir Nobahar

##### Position

Assistant Professor of Semnan University of Medical Sciences

##### Other areas of specialty/work

##### Street address

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

##### City

Semnan

##### Postal code

##### Phone

+98 23 3365 4170

##### Fax

##### Email

nobahar43@semums.ac.irNobahar43@yahoo.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Semnan University of Medical Sciences

##### Full name of responsible person

Monir Nobahar

##### Position

PhD Nursing

##### Other areas of specialty/work

##### Street address

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

##### City

Semnan

##### Postal code

##### Phone

+98 23 3365 4170

##### Fax

##### Email

Nobahar43@semums.ac.irNobahar43@yahoo.com

##### Web page address

---

**Person responsible for updating data**

nobahar43@semums.ac.ir  
**Web page address**

---

**Contact****Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Monir Nobahar

**Position**

Assistant Professor

**Other areas of specialty/work****Street address**

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

**City**

Semnan

**Postal code****Phone**

+98 23 3365 4170

**Fax****Email****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*

---