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
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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
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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