

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jan 2020

The effect of valerian on cognitive disorders in hemodialysis' patients

Protocol summary

Summary

Objective: To determine the effect of valerian on cognitive disorders 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. Completion of MMSE questionnaires and EEG (day after hemodialysis) is done 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.). Completion of MMSE questionnaires and EEG (day after hemodialysis) is done before and after each intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201606076318N7**
 Registration date: **2016-06-17, 1395/03/28**
 Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-06-17, 1395/03/28

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

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Recruitment status

Recruitment complete

Funding source

Semnan University of Medical Sciences

Expected recruitment start date

2016-05-26, 1395/03/06

Expected recruitment end date

2016-10-27, 1395/08/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of valerian on cognitive disorders in hemodialysis' patients

Public title

The effect of valerian on cognitive disorders 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

No age limit

Gender

Both

Phase

N/A

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 addressNursing and Paramedical Faculty, University of
Medical Sciences, Semnan**City**

Semnan

Postal code**Approval date**

2016-05-25, 1395/03/05

Ethics committee reference number

IR.SEMUMS.REC.1395.25

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**

Cognitive status

TimepointBefore 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, Cognitive status is measured by using
Electroencephalography (EEG) and MMSE questionnaire.

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). The score for total cognitive health is (25-30), for mild cognitive disorder is (21-24), for moderate disorder is (10-20) and for severe disorder is (<9). Information for each person will be recorded in their personal questionnaire.

Secondary outcomes

empty

Intervention groups**1****Description**

Group A uses Valerian capsules (Sedamin 530 mg, Goldaru Co.) 60 minutes before bedtime for one month. After one month (cleaning or wash out), the type of treatment between two groups is replaced, group A will receive placebo. Completion of Mini Mental State Examination (MMSE) questionnaires and EEG (day after hemodialysis) is done 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 or wash out), the type of treatment between two groups is replaced, group B will receive Valerian capsules (Sedamin 530 mg, Goldaru Co.). Completion of Mini Mental State Examination (MMSE) questionnaires and EEG (day after hemodialysis) is done 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 addressFaculty 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

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

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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

Associate Professor of Semnan University of Medical Sciences

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

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Full name of responsible person

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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*