Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparative investigating the effect of valerian and Gabapentin on restless legs syndrome and sleep quality in dialysis patients referring to the dialysis ward of Ali Ibn Abi Taleb Hospital of Rafsanjan, 2021

Protocol summary

Study aim

Comparison the effect of Valerian and Gabapentin on sleep quality and restless legs syndrome in dialysis patients referring to the dialysis ward of Ali Ibn Abitaleb Hospital of Rafsanjan, 2021

Design

Randomized, cross over clinical trial with control group

Settings and conduct

In this clinical trial, the study population are dialysis patients who will referring to the dialysis ward of Ali Ibn Abitaleb Hospital of Rafsanjan. Participants will select by convenience sampling method based on inclusion criteria and will allocate using the toss of coin. Demographic questionnaire, Pittsburgh Sleep Quality and International Restless Legs Syndrome questionnaires will complete in both groups before and after the duration of intervention. Participants will be divided into two groups of A (will receive Valerian) and B (will receive Gabapentin). After the end of the intervention, one month will be consider as a wash out period and then, both groups will replace.

Participants/Inclusion and exclusion criteria

Getting a score above 10 from the Restless Legs questionnaire; score above 5 of the Sleep Quality Questionnaire; age over 14 years old; signing the inform consent for participate in the study; satisfaction for taking drugs; BMI less than 30 and Blood pressure higher than 110/70 are inclusion criteria. Allergy to Valerian; having a physical disability; having mental disorders and being treated with psychiatric drugs; deafness or blindness; pregnancy and taking Gabapentin routinely before hand are exclusion criteria.

Intervention groups

Group A: patients will take Valerian (capsule: 530 mg) and in group B patients will take Gabapentin (capsule: 100 mg), for one month. In the next step, after the end of the intervention, one month will be consider as a wash out period and then, two groups will replace.

Main outcome variables

Score of restless legs syndrome; score of sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150713023190N9**
Registration date: **2021-10-19, 1400/07/27**
Registration timing: **prospective**

Last update: **2021-10-19, 1400/07/27**
Update count: **0**

Registration date

2021-10-19, 1400/07/27

Registrant information

Name
Tabandeh Sadeghi
Name of organization / entity
Rafsanjan University of Medical Sciences
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2022-04-20, 1401/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative investigating the effect of valerian and Gabapentin on restless legs syndrome and sleep quality in dialysis patients referring to the dialysis ward of Ali Ibn Abi Taleb Hospital of Rafsanjan, 2021

Public title

Comparison the effect of valerian and Gabapentin on restless legs syndrome and sleep quality in dialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Getting a score above 10 from the Restless Legs questionnaire Getting a score above 5 of the Sleep Quality Questionnaire Age over 14 years old Inform consent for participate in the study Satisfaction for taking drugs BMI less than 30 Blood pressure> 110/70

Exclusion criteria:

Allergy to valerian Having a physical disability Having mental disorders and being treated with psychiatric drugs Deafness or blindness pregnancy Taking Gabapentin routinely beforehand

Age

From **14 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

This is a cross over study. Initially, the patients will allocate into two groups by the toss of a coin. After the end of the intervention, one month will be consider as a wash out period and then, two groups will replace.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Rafsanjan University of Medical Sciences

Street address

Imam Ali Blvd

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Approval date

2021-10-02, 1400/07/10

Ethics committee reference number

IR.RUMS.REC.1400.136

Health conditions studied

1

Description of health condition studied

Restless leg syndrome

ICD-10 code

G25.81

ICD-10 code description

Restless legs syndrome

Primary outcomes

1

Description

Mean score of restless leg syndrome

Timepoint

Before and after the each of intervention

Method of measurement

International Restless Legs Syndrome Questionnaire

2

Description

Mean score of sleep quality

Timepoint

Before and after the each of intervention

Method of measurement

Pittsburgh Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group A: patients will take Sedamin (

capsule: 530 mg made by Isfahan Gol Daroo Company), as a single dose one hour before bedtime for one month.

Category

Treatment - Drugs

2

Description

Intervention group B: patients will take Gabapentin (capsule: 100 mg), as a single dose one hour before bedtime for one month.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Ibn Abitaleb Hospital

Full name of responsible person

Ali Mousavi

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rafsanjan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Iman Hajizadeh Khanaman

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Confidentiality of data
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable