

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 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)

Phone

+98 34 3425 5900

Email address

t.sadeghi@rums.ac.ir

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

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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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Latest degree

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Other areas of specialty/work

Nursery

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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