Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of a nasal drop of violet essential oil on the improvement of sleep quality in hemodialysis patients.

Protocol summary

Study aim
Determination of the effect of a nasal drop of violet essential oil on the improvement of sleep quality in hemodialysis patients.

Design
The clinical trial with two groups (intervention and control), pragmatic, double-blind, randomized

Settings and conduct
This study was conducted to determine the effect of nasal drops on hemodialysis patients in hemodialysis department of Vasei Hospital in Sabzevar. Clinical observant and participants will be unaware of how they are grouped. Patients will be randomly assigned to the intervention group (violet essential oil) and control (paraffin oil). The response to treatment was evaluated using the Pittsburgh Sleep Quality Index (PSQI) at the end of the thirty days after the intervention for both groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients aged 18 to 65 years, Have a score of 5 and more in sleep questionnaires, Being under dialysis for at least three months and continue dialysis at the same center. Exclusion Criteria: Infections of the upper respiratory tract, Cases of mental illness such as major depression, Schizophrenia, and mental retardation, Patients with infections, Malignancy or bad clinical conditions.

Intervention groups
Intervention group: Patients in this group are trained to receive 2 drops of violet essential oil (Dr. Mohammad bagher minaee laboratory) one time in each nostril for thirty days, in addition to a possible routine treatment, half an hour before bedtime. Control group: Patients in this group are trained to receive 2 drops of paraffin oil (Kimiagartoos pharmaceutical company) one time in each nostril for thirty days, in addition to a possible routine treatment, half an hour before bedtime.

Main outcome variables
The quality of sleep

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181006041252N8**
Registration date: **2019-01-25, 1397/11/05**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-25, 1397/11/05**
Update count: **0**

Registration date
2019-01-25, 1397/11/05

Registrant information

Name
Mohammad Sahebkar

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-12-29, 1397/10/08

Expected recruitment end date
2019-02-27, 1397/12/08

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Effect of a nasal drop of violet essential oil on the improvement of sleep quality in hemodialysis patients.

Public title
Effect of a nasal drop of violet essential oil on the improvement of sleep quality in hemodialysis patients.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients aged 18 to 65 years Have a score of 5 and more in sleep questionnaires Being under dialysis for at least three months Continue dialysis at the same center

Exclusion criteria:
Infections of the upper respiratory tract Cases of mental illness such as major depression, schizophrenia, mental retardation Patients with infections, malignancy, or bad clinical conditions

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **68**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization was conducted based on a permutation block by a statistical consultant using random allocation software and the output sequences A and B are available to the researcher, Accordingly, 17 blocks are allocated to patients, in each block, 2 were from following groups, treatment group A and group B. Eventually, after completing the blocks, Group A and B are treated with Violet flower and Paraffin oil, respectively. First, we determine all foursome modes in which half of the individuals are assigned to group A and the other half to group B. Then we assign one of the digits 1 to 6 to each of the foursome combinations (which includes six modes). In the next step, we must randomly select 17 blocks of four and write their combinations in succession. For this we have to make 17 samplings with replacement from a six-member community; 17 times, choose a random number between 1 and 6 and this process will continue until the end of the sampling and the difference between the two groups will not exceed a maximum of two (half the size of the block).

Blinding (investigator's opinion)
Double blinded

Blinding description
Each person will be assigned a study code A and B, which will only be known to the researcher of the type of groups. The clinical observant and the participants are unaware of the groups. It should be noted that violet essential oil and Paraffin oil are similar in appearance, color, and packaging.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Sabzevar University of Medical Sciences

Street address
Sabzevar University of Medical Sciences, Tohid Blvd, Sabzevar city

City
Sabzevar

Province
Razavi Khorasan

Postal code
9617913114

Approval date
2019-01-13, 1397/10/23

Ethics committee reference number
IR.MEDSAB.REC.1397.095

Health conditions studied

1

Description of health condition studied
The quality of sleep

ICD-10 code
F15.282

ICD-10 code description
Other stimulant dependence with stimulant-induced sleep disorder

Primary outcomes

1

Description
The quality of sleep

Timepoint
At the beginning of the study (before the intervention), 2 and 4 weeks after the intervention

Method of measurement
Pittsburgh Sleep Quality Index (PSQI)

Secondary outcomes

1

Description

Itching

Timepoint

At the beginning of the study (before the intervention), 2 and 4 weeks after the intervention

Method of measurement

5-D itch questionnaire

2

Description

Patient Satisfaction

Timepoint

At the beginning of the study (before the intervention), 2 and 4 weeks after the intervention

Method of measurement

Treatment acceptability questionnaire (TAD)

Intervention groups

1

Description

Intervention group: Patients in this group are trained to receive 2 drops of violet essential oil (Dr. Mohammad bagher minaee Laboratory) one time in each nostril for thirty days, in addition to a possible routine treatment, half an hour before bedtime.

Category

Treatment - Drugs

2

Description

Control group: Patients in this group are trained to receive 2 drops of paraffin oil (Kimiagartoos pharmaceutical company) one time in each nostril for thirty days, in addition to a possible routine treatment, half an hour before bedtime.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Vasei hospital

Full name of responsible person

Marzieh Naghdi

Street address

Vasei Hospital, Asadabady Ave., Sabzevar Town

City

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Postal code

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Naghdi.marzieh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Dr. Fereshte Ghorat

Street address

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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

Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

Dr. Fereshte Ghorat

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Contact

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Other areas of specialty/work
Traditional Medicine

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Medical student

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Medical doctor

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General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available