

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jul 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)

##### Phone

+98 51 4401 8337

##### Email address

sahebkar@medsab.ac.ir

##### 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**  
Sabzevar  
**Province**  
Razavi Khorasan  
**Postal code**  
9613873136  
**Phone**  
+98 51 4401 1014  
**Email**  
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**  
Sabzevar University of Medical Sciences, Tohid Blvd., Sabzevar Town  
**City**  
Sabzevar  
**Province**  
Razavi Khorasan  
**Postal code**  
9617913114  
**Phone**  
+98 51 4401 8319  
**Email**  
Drghorat@gmail.com  
**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  
**Street address**  
Sabzevar University of Medical Sciences, Tohid Blvd., Sabzevar Town  
**City**  
Sabzevar  
**Province**  
Razavi Khorasan  
**Postal code**

9617913114

**Phone**

+98 51 4401 8319

**Email**

drghorat@gmail.com

## Person responsible for scientific 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

**Street address**

Sabzevar University of Medical Sciences, Tohid Blvd.,  
Sabzevar Town

**City**

Sabzevar

**Province**

Razavi Khorasan

**Postal code**

9617913114

**Phone**

+98 51 4401 8319

**Email**

drghorat@gmail.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Sabzevar University of Medical Sciences

**Full name of responsible person**

Marzieh Naghdi

**Position**

Medical student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

Sabzevar University of Medical Sciences, Tohid Blvd.,  
Sabzevar Town

**City**

Sabzevar

**Province**

Razavi Khorasan

**Postal code**

9617913114

**Phone**

+98 51 4401 8337

**Email**

Naghdi.marzieh@gmail.com

## 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