

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### The Effect of Viola odorata oil nasal drop on elderly sleep quality

#### Protocol summary

##### Summary

The purpose of this study is to examine the effect of Viola odorata oil nasal drop on elderly sleep quality. This clinical trial, includes two groups and is single blinded. In this study, 60 elderly people with poor sleep quality were studied in three Sabzevar centers in 1395. Inclusion criteria include: Not suffering from mental illness; Respiratory diseases and Musculoskeletal pains and Exclusion criteria include: Discontinue use of Viola odorata oil for any reason and any allergic reaction during the study. At first Petersburg's Sleep Quality Measurement Questionnaire was completed by the researcher for eligible individuals and the elderly people with a sleep score of at least 5 were put on the name list. Then the names were divided into two groups of intervention (violet oil) and placebo (paraffin oil) with the coin toss method. The method of doing the work was practically done by the researcher for both groups. In the intervention group, two drops of violet oil were dropped by a researcher with a dropper in each nostril of the elderly, and then the elder was asked to explain the method. This work was done half an hour before bedtime by the elder for one month and the questionnaire was completed in three steps before, 15 days and one month after the beginning of the study and at the end of each week, a follow up was conducted. All steps in the placebo group were also performed, but paraffin oil was used instead of violet oil.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016082229470N1**

Registration date: **2017-11-03, 1396/08/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-11-03, 1396/08/12

##### Registrant information

###### Name

Malihe Sadat Hejazyan

###### Name of organization / entity

Sabzevar University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51444663522

###### Email address

hejazyanm93@medsab.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Sabzevar University of Medical Sciences, College of Nursing

##### Expected recruitment start date

2016-10-22, 1395/08/01

##### Expected recruitment end date

2017-04-19, 1396/01/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of Viola odorata oil nasal drop on elderly sleep quality

##### Public title

The Effect of Viola odorata drop on elderly sleep quality

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: Willingness to Cooperation; Older people over the age of 60; Not suffering from mental illness such as severe depression; Drug abuse; Other

diseases such as Parkinson and Alzheimer; Respiratory diseases; Musculoskeletal pains; Having a score higher than 5 in the Petersburg Sleep Quality Questionnaire. Exclusion criteria: Discontinue use of Viola odorata oil for any reason; Consumption of Viola odorata by the client contrary to the prescribed dose; Any allergic reaction to Viola odorata oil during the study.

**Age**

From **60 years** old to **75 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description****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**

Pardise, Tohid street, Sabzevar

**City**

sabzevar

**Postal code****Approval date**

2016-10-10, 1395/07/19

**Ethics committee reference number**

ir.medsab.rec.1395.76

**Health conditions studied****1****Description of health condition studied**

sleep quality

**ICD-10 code**

G47.9

**ICD-10 code description**

Sleep disorder, unspecified

**Primary outcomes****1****Description**

sleep quality

**Timepoint**

The questionnaire was completed in three steps before, 15 days and one month after the beginning of the study.

**Method of measurement**

Petersburg's Sleep Quality Measurement Questionnaire

**Secondary outcomes**

empty

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

In the intervention group, each night, half an hour before bedtime, two drops of violet oil from the Tooba company were dropped in each nostril for one month.

**Category**

Treatment - Other

**2****Description**

In the placebo group, each night, half an hour before bedtime, two drops of paraffin oil were dropped in each nostril for one month.

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Retirement center

**Full name of responsible person**

malihe Hejazyan

**Street address**

Sabzevar

**City**

Sabzevar

**2****Recruitment center****Name of recruitment center**

Old people's home

**Full name of responsible person**

malihe Hejazyan

**Street address**

sabzevar

**City**

Sabzevar

### **3**

#### **Recruitment center**

**Name of recruitment center**

Health Center

**Full name of responsible person**

malihe Hejazyan

**Street address**

Sabzevar

**City**

Sabzevar

#### **Sponsors / Funding sources**

### **1**

#### **Sponsor**

**Name of organization / entity**

Research Council of Sabzevar University of Medical Sciences

**Full name of responsible person**

Dr Mohammad Mohammadzade

**Street address**

Sabzevar University of Medical Sciences, Tohid Shahr Blvd, Sabzevar

**City**

Sabzevar

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Research Council of Sabzevar 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**

Sabzevar University of Medical Sciences

**Full name of responsible person**

Malihe Hejazyan

**Position**

MSc Student of Geriatric Nursing

**Other areas of specialty/work**

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#### **Person responsible for scientific inquiries**

##### **Contact**

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Javad Ganjlo

**Position**

Faculty member of Medical Surgical Nursing group, MSc of Nursing

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#### **Person responsible for updating data**

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malihehejazyan237@gmail.com

**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*