

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

Paradise, 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

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Javad Ganjlo

Position

Faculty member of Medical Surgical Nursing group, MSc of Nursing

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

Malihe Hejazyan

Position

MSc Student of Geriatric Nursing

Other areas of specialty/work

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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