

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

The effectiveness of violet syrup on insomnia reduction in patients with obsessive compulsive disorder or depression

Protocol summary

Summary

This double-blinded clinical trial study aims to consider the effect of Violet Syrup on insomnia reduction in patients with depression or obsessive-compulsive disorder in Iran. Insomnia reduction will be considered using the Pittsburgh questionnaire. The inclusion criteria: sleeplessness score more than 5 based on Pittsburgh questionnaire, signs and symptoms of depression and obsessive-compulsive disorder, consent and commitment for participation in the study, consumption of SSIR drug for at least one month, no history of physical illnesses, psychotic psychiatric disorder and generalized anxiety disorder. Exclusion criteria: history of sleep apnea, use of pharmaceutical and non-pharmaceutical treatments for insomnia. The study population includes patients with depression or obsessive-compulsive disorder along with insomnia. A total number of 80 patients with depression (20 patient in Violet Syrup and 20 patient in placebo Syrup) or obsessive-compulsive disorder (20 patient in Violet Syrup and 20 patient in placebo Syrup) will be randomly allocated to the intervention and control groups. In this research, the study subjects and data monitoring committee will be blinded. Patients in the study and control groups will receive Violet Syrup and placebo, respectively. The medication and placebo will not be manufactured by the researcher. Simple randomization of subjects will be provided using a random number table.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017040833294N1**

Registration date: **2017-09-26, 1396/07/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-09-26, 1396/07/04

Registrant information

Name

Maryam Shayesteh

Name of organization / entity

Iranian Traditional Medicine Department, Shahed University

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Shahed University

Expected recruitment start date

2017-09-15, 1396/06/24

Expected recruitment end date

2018-02-13, 1396/11/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of violet syrup on insomnia reduction in patients with obsessive compulsive disorder or depression

Public title

Assessment of Viola Odorata efficacy on insomnia in patients with obsessive compulsive disorder or depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: no history of psychotic psychiatric disorder and generalized anxiety disorder, no history of opiate using and neurological diseases such as Parkinson and Alzheimer, no sleep apnea, lack of simultaneous use of pharmaceutical and non- pharmaceutical treatments for insomnia, no pregnancy and lactation
Exclusion criteria: history of physical illness along with pulmonary diseases, rhinitis allergy, cardiovascular diseases, infectious diseases, hepatic and renal failure, cancers, psychiatric disorder and generalized anxiety disorder; history of smoking and opiate using, history of neurological diseases such as Parkinson and Alzheimer, sleep apnea, simultaneous use of pharmaceutical and non- pharmaceutical treatments for insomnia, pregnant and lactating women, drug avoidance for >20% of total dosage of prescribed drug

Age

From **16 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double 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 Shahed University

Street address

Abdollahzadeh st, Keshavarz blv

City

Tehran

Postal code

Approval date

2017-04-09, 1396/01/20

Ethics committee reference number

IR Shahed REC.1395.232

Health conditions studied

1

Description of health condition studied

Obsessive Compulsive Disorder

ICD-10 code

F42

ICD-10 code description

Obsessive Compulsive Disorder

2

Description of health condition studied

Insomnia

ICD-10 code

F51

ICD-10 code description

Insomnia

3

Description of health condition studied

Depression

ICD-10 code

F32

ICD-10 code description

Depression

4

Description of health condition studied

Insomnia

ICD-10 code

F51.9

ICD-10 code description

Insomnia

Primary outcomes

1

Description

Insomnia

Timepoint

Before intervention (baseline), after one month (post)

Method of measurement

Pittsburgh Questionnaire

Secondary outcomes

1

Description

Depression

Timepoint

Before intervention (baseline), after one month (post)

Method of measurement

Beck Questionnaire

2

Description

Obsessive Compulsive Disorder

Timepoint

Before intervention (baseline), after one month (post)

Method of measurement

YBOCS Questionnaire

Intervention groups

1

Description

Drug use syrup of violets to 5 ml every 12 hours in the morning and at night.

Category

Treatment - Drugs

2

Description

Placebo syrup use to 5 ml every 12 hours in the morning and at night.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Psychiatric Clinic of Imam Hossein

Full name of responsible person

Maryam Shayesteh (Physician, Student of Iranian Traditional Medicine)

Street address

Madani St

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Deputy of Research and Technology of Shahed University

Full name of responsible person

Dr. Zahra Kiasalari

Street address

Shahed University, Khalij Fars Express Way

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Deputy of Research and Technology of Shahed University

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Vice chancellor for research, Deputy of Research and Technology of Shahed University

Full name of responsible person

Eng. Mohamad Kamalinejad (pharmacist)

Street address

Near the Intersection of Niayesh, Vali Asr st

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Deputy of Research and Technology of Shahed University

Proportion provided by this source

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

Iranian Traditional Medicine Department, Shahed University

Full name of responsible person

Maryam Shayesteh

Position

MD, PhD Student in Iranian Traditional Medicine

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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