

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of use of Valeriana Officinalis On psychological symptoms and sleep disorders in patient with chronic schizophrenia admitted in Sina hospital Jouneghan

Protocol summary

Study aim

Determination the effect of Valeriana Officinalis On psychological symptoms and sleep disorders in patient with chronic schizophrenia admitted in Sina hospital Jouneghan

Design

In this study, a double-blind, placebo-controlled clinical trial is a single-centered study, in which 80 patients with schizophrenia with inclusion criteria are divided into two groups. Inrervention group, in addition to routine drugs, one hour before bedtime, one capsule of sedamine and in control group, in addition to routine drugs capsule containing 50 mg of starch as a placebo receive and after three months the therapeutic effects of the capsule of sodium will be examined.

Settings and conduct

Clinical trial; Sina Psychiatric Hospital; placebo-controlled

Participants/Inclusion and exclusion criteria

Inclusion criteria: Chronic schizophrenia based on physician diagnosis and diagnostic criteria DSM V
Exclusion criteria: The probable problems associated with the use of herbal medicines mentioned during the study; discharging and no possibility of participation in the study due to absence in the hospital

Intervention groups

Inrervention group, in addition to routine drugs, one hour before bedtime, one capsule of sedamine and in control group, in addition to routine drugs capsule containing 50 mg of starch as a placebo receive and after three months the therapeutic effects of the capsule of sodium will be examined.

Main outcome variables

psychological symptoms and sleep disorder

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120709010222N18**

Registration date: **2018-01-12, 1396/10/22**

Registration timing: **prospective**

Last update: **2018-01-12, 1396/10/22**

Update count: **0**

Registration date

2018-01-12, 1396/10/22

Registrant information

Name

Zahra Keivani

Name of organization / entity

Shahrekord University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 38 1222 0016

Email address

keivani@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2018-07-23, 1397/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of use of Valeriana Officinalis On psychological symptoms and sleep disorders in patient with chronic schizophrenia admitted in Sina hospital Jouneghan

Public title

Effect of use of Valeriana Officinalis On psychological symptoms and sleep disorders in patient with chronic schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Chronic schizophrenia based on physician diagnosis and diagnostic criteria DSM V

Exclusion criteria:

The probable problems associated with the use of herbal medicines mentioned during the study Discharging or no possibility of participation in the study due to absence in the hospital

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description

Stratified Random Sampling

Blinding (investigator's opinion)

Double blinded

Blinding description

The investigator and the patient will have no information about the content of the capsules

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahrekord University of Medical Sciences

Street address

Kashani street, shahrekord university of medical sciences, shahrekord

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

88187187

Approval date

2017-02-05, 1395/11/17

Ethics committee reference number

IR.SKUMS.REC.1395.250

Health conditions studied

1

Description of health condition studied

schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

psychological symptoms

Timepoint

Three weeks after intervention

Method of measurement

Anderson's Pittsburgh Questionnaires

2

Description

Sleep disorder

Timepoint

Three weeks after intervention

Method of measurement

Anderson's Pittsburgh Questionnaires

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: every night, One hour before bedtime, receive one capsule of 350mg sedemin per oral.

Category

Treatment - Drugs

2

Description

Control group: receive 50 mg capsule containing starch as a placebo per oral.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina hospital Jouneghan

Full name of responsible person

Masoud Nikfarjam

Street address

Farsan city,3 km from Jangqan city

City

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Chahar-Mahal-va-Bakhtiari

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88187187

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Email

nikmas140@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Dr. Kamal Solati

Street address

Kashani street, shahrekord university of medical sciences, shahrekord

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kamal_solati@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Vice chancellor for research of Shahrekord University of Medical Science

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

Shahre-kord University of Medical Sciences

Full name of responsible person

Masoud Nikfarjam

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Farsan city,3 km from Jangqan city,Sina hospital Jouneghan

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Innominate questionnaire

When the data will become available and for how long

six months

To whom data/document is available

co authors

Under which criteria data/document could be used

publish

From where data/document is obtainable

co authors

What processes are involved for a request to access data/document

Six months from the time of the approval of the project
to the publication of the documentation

Comments