

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Aug 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. Intervention 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

Intervention 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		Shahrekord
Public title		Province
Effect of use of Valeriana Officinalis On psychological symptoms and sleep disorders in patient with chronic schizophrenia		Chahar-Mahal-va-Bakhtiari
Purpose		Postal code
Treatment		88187187
Inclusion/Exclusion criteria		Approval date
Inclusion criteria:		2017-02-05, 1395/11/17
Chronic schizophrenia based on physician diagnosis and diagnostic criteria DSM V		Ethics committee reference number
Exclusion criteria:		IR.SKUMS.REC.1395.250
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		Health conditions studied
No age limit		<u>1</u>
Gender		Description of health condition studied
Both		schizophrenia
Phase		ICD-10 code
3		F20
Groups that have been masked		ICD-10 code description
- Participant - Outcome assessor		Schizophrenia
Sample size		Primary outcomes
Target sample size: 80		<u>1</u>
Randomization (investigator's opinion)		Description
Randomized		psychological symptoms
Randomization description		Timepoint
Stratified Random Sampling		Three weeks after intervention
Blinding (investigator's opinion)		Method of measurement
Double blinded		Anderson's Pittsburgh Questionnaires
Blinding description		
The investigator and the patient will have no information about the content of the capsules		
Placebo		2
Used		Description
Assignment		Sleep disorder
Parallel		Timepoint
Other design features		Three weeks after intervention
		Method of measurement
		Anderson's Pittsburgh Questionnaires
Secondary Ids		Secondary outcomes
empty		empty
Ethics committees		Intervention groups
<u>1</u>		<u>1</u>
Ethics committee		Description
Name of ethics committee		Intervention group:every night, One hour befor bedtime, receive one capsule of 350mg sedemin per oral.
Ethics Committee of Shahrekord University of Medical Sciences		Category
Street address		Treatment - Drugs
Kashani street, shahrekord university of medical sciences, shahrekord		2
City		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

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

88187187

Phone

+98 38 2746 3331

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

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

88187187

Phone

+98 38 3334 2414

Email

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

Street address

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

City

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Person responsible for updating data

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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