Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Nov 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 receveive 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 receveive 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)

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+98 38 1222 0016

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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 befor 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

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Shahrekord

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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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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 questionaire
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