Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

The Effect of Valeriana 0fficinalis (Valerian) Oral Extract on Sleep Quality and Fatigue of Patients with Chronic Obstructive Pulmonary Disease

Protocol summary

Study aim

Determination of the Effect of Valeriana 0fficinalis (Valerian) on Sleep Quality and Fatigue of Patients with Chronic Obstructive Pulmonary Disease

Design

Random sampling, test and control groups, total number of samples 60, blind three-way and in phase 3 with parallel groups

Settings and conduct

افراد مراجعه کننده به بیمارستان های وابسته به دانشگاه آزاد اسلامی واحد علوم پزشکی که معیارهای ورود به پژوهش را دارند انتخاب خواهند شد. پژوهش حاضر به صورت سه سوکور انجام خواهد گرفت.

Participants/Inclusion and exclusion criteria

Entry requirements: Medical diagnosis and clinical signs of the disease in stage one and two diseases, over the age of 18 years, are associated with some degree of fatigue and sleep disorders. Lack of other diseases, drug allergy, pregnancy, ability to read and write, non-use of drugs and hypnotics Exit Conditions: Any changes in sleep conditions, any physical and mental illness during the study, no capsule consumption for a maximum of 7 days during a month, primary diagnosis of obstructive apnea, patient's personal desire to withdraw Study

Intervention groups

In this study, the capsule is prepared by a pharmacologist after extraction by a pharmacologist after extraction by means of a capsule filling machine. In the test group, oral licorice capsule contains 300 mg of the root of the plant and the oral administration of the capsule containing the control group Starch will be given at a rate of 50 mg, which will be administered to the two groups for four weeks, once a day (one hour before bedtime). The fatigue researcher then examines the Fatigue Severity and Sleep Quality Questionnaire by Pittsburgh Questionnaire before the intervention, after 2 weeks from the onset of the intervention and again at the end of the 4th week of intervention.

Main outcome variables

طزFatigue Test by Fatigue Severity and Sleep Quality Questionnaire by Pittsburgh Questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180413039292N1**
Registration date: **2018-04-27, 1397/02/07**
Registration timing: **prospective**

Last update: **2018-04-27, 1397/02/07**
Update count: **0**

Registration date

2018-04-27, 1397/02/07

Registrant information

Name

Samaneh Shahabi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-29, 1397/02/09

Expected recruitment end date

2018-05-30, 1397/03/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The Effect of Valeriana 0fficinalis (Valerian) Oral Extract on Sleep Quality and Fatigue of Patients with Chronic Obstructive Pulmonary Disease

Public title
The Effect of Valeriana 0fficinalis (Valerian) on Sleep Quality and Fatigue of Patients with Chronic Obstructive Pulmonary Disease

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of chronic obstructive pulmonary disease in stage one and two diseases, based on medical history and clinical symptoms and patient records Having some degree of fatigue, according to the Fatigue Severity Index (MFI), the total score obtained from fatigue in patients between 20 to 100 can be. The higher the score, the higher the fatigue Earn more than 6 points in response to Pittsburgh Sleep Quality Index Stable patient clinical condition (no acute problems) and no other chronic disease Aged 18 years and older Ability to read and write Persian texts Both sexes, both male and female Do not use other herbs during the intervention Not having a history of eczema and allergies to plants Complete vigilance Not having drug and alcohol addiction Not taking patients from benzodiazepines, sedative drugs, sleep deprivation and opiate during intervention Not Pregnant women of childbearing age

Exclusion criteria:
The occurrence of any physical and mental illness during the study that causes sleep disorder Existence of any significant changes in sleep conditions in an unpredictable way, including travel, change of location and ... Do not take capsules for up to 7 days during a month The patient's personal desire to quit for any reason Early diagnosis of obstructive apnea

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Samples are firstly selected through available sampling from those referring to the criteria for entering the research. In order to ensure that the conditions of the study and to avoid bias in the face of the interventional conditions, the random allocation method will be used for placement of patients in the control and test groups. To do this, a list of all patients with chronic obstructive pulmonary disease referring to the educational hospitals of the Islamic Azad University of Medical Sciences that have criteria for entering the study is provided and numbered to each patient. Then they will be randomly selected using the random sample table and will be randomly assigned to two groups

Blinding (investigator's opinion)
Triple blinded

Blinding description
The study will be triple-blind so that the packaging of capsules, one shape, and capsules A and B will be packaged by the pharmacist. The capsules of the two groups are united in similar formulations. Medicines without a name are prescribed by the code and the findings will be recorded in a separate form. The researcher will not be informed about the samples as well as analyzing the statistical information about the contents of the capsules, and only the pharmacist will inform the group upon completion of the statistical analysis of the content of the capsules. Therefore, the present study will be carried out in triple succor.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Islamic Azad University, Tehran Medical Sciences

Street address
Unit 1 and 2, No 1, Akhavar Blvd Alley, Ataei Alley, Hashemi Avenue, Moein Shaheedeh Blve

City
Tehran

Province
Tehran

Postal code
1349837793

Approval date
2017-07-25, 1396/05/03

Ethics committee reference number
IR.IAU.TMU.REC.1396.69

Health conditions studied

1

Description of health condition studied
Patients with Chronic Obstructive Pulmonary Disease

ICD-10 code
J41.1
ICD-10 code description
Mucopurulent chronic bronchitis

Primary outcomes

1

Description
Fatigue score in MFI fatigue questionnaire, sleep quality score in Pittsburgh questionnaire
Timepoint
Fatigue measurements were performed by the MFI fatigue and sleep quality questionnaire by Pittsburgh questionnaire before the intervention, after 2 weeks of the intervention and again at the end of week 4 after taking valerian
Method of measurement
MFI Fatigue Inventory, Pittsburgh Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Oral capsule of Valerian extract containing 300 mg of the root of the plant for four weeks, once a day (one hour before bedtime)
Category
Rehabilitation

2

Description
Control group: Oral capsule containing starch 50 mg for four weeks, once a day (one hour before bedtime)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Buali Hospital
Full name of responsible person
Samaneh Shahabi
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No 1, Blind Alley Ashenavar, Alley Ataii, Hashemi Street, Ostad Modin Boulevard
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Recruitment center
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Amir Al-Momenin Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Islamic Azad university
Proportion provided by this source
1
Public or private sector
Private
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
Islamic Azad University
Full name of responsible person
Samaneh Shahabi
Position
Masters student
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available