

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Evaluation of the effect of *Withania somnifera*'s ethanolic extract on patients with obsessive-compulsive disorder

Protocol summary

Summary

The purpose of this study is to find new ways for the treatment of patients with Obsessive-Compulsive disorder (OCD), with the use of *Withania somnifera*. This is a randomized, double-blind, placebo-controlled, single center, second phase clinical trial. The study population is 30 patients that are diagnosed with OCD. Inclusion criteria: 1) Diagnosis of OCD according to DSM-IV TR. 2) Treatment with SSRI drugs with adequate dose and duration. Exclusion criteria: 1) Pregnancy. 2) Lactation. 3) Comorbidity with other acute psychological disorders. 4) Drug abuse. 5) Liver and renal disorders. 6) Usage of other drugs that have an effect on OCD (Lithium, Gabapentin, Buspirone...). Sample size: Since this is a pilot study, the sample size is limited to 30 patients (15 in each group). In this study either capsules containing *Withania somnifera*'s freeze dried extract (in treatment group) or capsules containing Lactose (in placebo group) is added to the patient's regimen, and its effect is evaluated. The study is carried out in a 6 weeks course, during which the change in the patient's symptoms is evaluated. The outcome of this study is the effect of *Withania somnifera*'s extract on the severity of OCD symptoms, which is evaluated by "Yale Brown" test.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015070523079N1**
Registration date: **2015-08-10, 1394/05/19**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-08-10, 1394/05/19

Registrant information

Name

Seyyedeh Pardis Jahanbakhsh

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3843 9270

Email address

jahanbakhshp891@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2015-02-20, 1393/12/01

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of *Withania somnifera*'s ethanolic extract on patients with obsessive-compulsive disorder

Public title

Evaluating the effect of *Withania Somnifera* on obsession

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1) Diagnosis of OCD according to DSM-IV TR. 2) Treatment with SSRI drugs with adequate dose and duration. Exclusion criteria: 1) Pregnancy. 2) Lactation. 3) Comorbidity with other acute psychological disorders. 4) Drug abuse. 5) Liver and renal disorders. 6)

Usage of other drugs that have an effect on OCD (Lithium, Gabapentin, Buspirone...).

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

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**

Committee for Medical Research Ethics, Mashhad University of Medical Sciences

Street address

Central Organization of University, Daneshgah St., Mashhad, Iran

City

Mashhad

Postal code**Approval date**

2015-01-17, 1393/10/27

Ethics committee reference number

930824

Health conditions studied**1****Description of health condition studied**

Obsessive-compulsive disorder

ICD-10 code

F42.2

ICD-10 code description

Mixed obsessional thoughts and acts

Primary outcomes**1****Description**

Severity of OCD symptoms

Timepoint

before intervention, 6 weeks after starting the intervention

Method of measurement

Yale Brown Obsessive Compulsive Scale

Secondary outcomes

empty

Intervention groups**1****Description**

Capsuls containing freeze dried ethanolic extracts of Withania somnifera, equivalent to 2 grams of Withania somnifera's roots, divided to 4 times a day (500 miligrams each), for 6 weeks

Category

Treatment - Drugs

2**Description**

Capsuls similar to the treatment group but without Withania somnifera's ethanolic extract, containing 250 miligrams of lactose, 4 times a day for 6 weeks

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Pharmaceutical Sciences Research Center, Mashhad University of Medical Sciences

Full name of responsible person**Street address****City**

Mashhad

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Mashhad University of Medical Sciences, Daneshgah st.

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Mashhad

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

Yes

Title of funding source
Mashhad University of Medical Sciences
Proportion provided by this source

100

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
Mashhad University of Medical Sciences

Full name of responsible person
Pardis Jahanbakhsh

Position
Pharm D student

Other areas of specialty/work

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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