

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Assessment of Withania somnifera root extract adequacy in patients with generalized anxiety disorder: A randomized, double-blind, placebo-controlled trial

#### Protocol summary

##### Study aim

The aim of this study is to assess the adequacy of W. somnifera root extract as an alternative therapy to standard GAD treatment.

##### Design

Forty patients were randomly selected for participation in the treatment group (W. somnifera extract, 1g/day; n = 22) or the placebo group (n = 18).

##### Settings and conduct

This general anxiety study was conducted at the site of Ibn Sina Hospital as a double blind controlled clinical trial in 2015. Patients and researchers (physician) did not know the type of intervention group.

##### Participants/Inclusion and exclusion criteria

The GAD patients according to DSM-IV-TR who had been under the treatment of SSRI drugs were included. Exclusion criteria were pregnancy and lactation, comorbidity with other acute psychological disorders, drug abuse and physical disorders which cause anxiety.

##### Intervention groups

treatment group (W. somnifera extract, 1g/day; n = 22) or the placebo group (n = 18). All patients were under treatment with Selective Serotonin Re-uptake Inhibitors (SSRIs), and were prescribed 1 capsules of the extract or placebo per day for six weeks

##### Main outcome variables

The Hamilton anxiety rating scale (HAM-A) was used in order to assess the severity of GAD symptoms at baseline and at the second and sixth week of the trial.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180615040105N1**  
Registration date: **2018-07-03, 1397/04/12**

Registration timing: **retrospective**

Last update: **2018-07-03, 1397/04/12**

Update count: **0**

##### Registration date

2018-07-03, 1397/04/12

##### Registrant information

###### Name

Asieh Karimani

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3705 4262

###### Email address

karimania921@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2014-08-23, 1393/06/01

##### Expected recruitment end date

2015-08-23, 1394/06/01

##### Actual recruitment start date

2014-08-23, 1393/06/01

##### Actual recruitment end date

2016-07-27, 1395/05/06

##### Trial completion date

empty

##### Scientific title

Assessment of Withania somnifera root extract adequacy in patients with generalized anxiety disorder: A randomized, double-blind, placebo-controlled trial

##### Public title

effect of Withania somnifera root extract in generalized

anxiety disorder

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
diagnosed as GAD patients according to the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision (DSM-IV-TR) they had to be under the treatment of SSRI drugs with adequate dose and duration

**Exclusion criteria:**  
pregnancy and lactation comorbidity with other acute psychological disorders drug abuse and physical disorders which cause anxiety every accident such as death or immigration

**Age**  
No age limit

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**  
Target sample size: **40**  
Actual sample size reached: **40**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
simple randomization was done by use of computer generated random numbers. Investigators and participants were unaware of upcoming allocations.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
Medication and placebo were prepared in capsule form and in a similar way at the Faculty of Pharmacy, so that the patient and the evaluator (physicians) did not know the specific intervention.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of mashhad University of Medical Sciences

##### Street address

Psychiatry and Behavioral Sciences Research Center,

Mashhad University of Medical Sciences, Mashhad, Iran

#### City

mashhad

#### Province

Razavi Khorasan

#### Postal code

91778-99191

#### Approval date

2014-07-26, 1393/05/04

#### Ethics committee reference number

IR.MUMS.REC.1393.137

## Health conditions studied

### 1

#### Description of health condition studied

generalized anxiety disorder

#### ICD-10 code

F41.1

#### ICD-10 code description

Generalized anxiety disorder

## Primary outcomes

### 1

#### Description

Anxiety score in Hamilton Test

#### Timepoint

At the onset of the study (before the intervention) and weeks 2, 6

#### Method of measurement

Anxiety Evaluation by Hamilton Test

## Secondary outcomes

### 1

#### Description

quality life score

#### Timepoint

the onset of the study, second and sixth week

#### Method of measurement

Score based on Hamilton test

## Intervention groups

### 1

#### Description

Intervention group: 22 patients received one capsule wich contains 1 g W. somnifera extract/day for six weeks.

#### Category

Treatment - Other

### 2

#### Description

Control group:18 patients received placebo (similar

capsule filled with lactose), one capsule/day for six weeks.

**Category**  
Placebo

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

ibne Sina hospital

**Full name of responsible person**

Ali Akhondpour Manteghi

**Street address**

Psychiatry and Behavioral Sciences Research Center,  
Mashhad University of Medical Sciences, Mashhad,  
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Mohamadpoorah@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr. Mohsen Tafaghodi

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psychiatry and Behavioral Sciences Research Center,  
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**Grant name**

**Grant code / Reference number**

922815

**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**

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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Asieh Karimani

**Position**

PhD student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Medical Pharmacy

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## Person responsible for scientific inquiries

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**Position**

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**Latest degree**

Ph.D.

**Other areas of specialty/work**

Toxicology

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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**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

Part of the data, such as information on the main  
consequence of the protective agent, can be used

**When the data will become available and for how long**

Start the access period from 1398

**To whom data/document is available**

for all the investigators

**Under which criteria data/document could be used**

Researchers for further studies

**From where data/document is obtainable**

Dr. Ali Akhondpour Manteghi manteghia@mums.ac.ir

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

Immediately after reviewing the terms of the applicant

**Comments**