

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 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.

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

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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

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180615040105N1**

Registration date: **2018-07-03, 1397/04/12**

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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Dr. Mohsen Tafaghodi

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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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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