

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Effect of *Withania somnifera* Root Extract on Anxiety Symptoms in Children with Attention deficit and Hyperactivity Disorder

#### Protocol summary

##### Study aim

Improving the delivery and treatment of anxiety symptoms in ADHD children and increasing satisfaction levels.

##### Design

Randomized clinical trial

##### Settings and conduct

Children Psychiatric Clinic of Ibn Sina Hospital in Mashhad. Referring children who are interviewed and diagnosed by the pediatric psychiatric specialist are included in the study. After obtaining informed consent from their legal guardians, they are randomly divided into two groups of case and control according to the random numbers table. RCMA questionnaire to assess the level of anxiety in all patients. The case group, in addition to the standard ADHD treatment, is treated with 10 mg capsules of *Whitney Sinnifera* root and is added to the standard treatment of ADHD treatment in the oral administration of placebo capsule. All children in weeks 3 and 6 again tested RCMA and the ADHD scoring scale was also filled by a psychiatrist's assistant during the weeks mentioned.

##### Participants/Inclusion and exclusion criteria

28 children with attention deficit and hyperactivity disorder, who have shown anxiety symptoms. Their age ranges from 7 to 12 years old and they have been receiving ADHD treatment for 3 months, and informed consent has been completed by legal guardians. Exit criteria include the patient's unwillingness to continue to participate in a research project for systemic and psychiatric illnesses.

##### Intervention groups

Intervention group: *Withania somnifera* capsule is given orally at a dose of 10 mg once a day for 6 weeks. treatment-drugs Control group: A placebo capsule similar to that of *Withania Somnifera* is given orally at a dose of 10 mg once a day for 6 weeks.

##### Main outcome variables

Investigating the effect of *Withania somnifera* on

symptoms of anxiety in children with ADHD. Evaluation of the effect of *withania somnifera* on the ADHD symptoms.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180723040567N1**

Registration date: **2018-11-10, 1397/08/19**

Registration timing: **retrospective**

Last update: **2018-11-10, 1397/08/19**

Update count: **0**

##### Registration date

2018-11-10, 1397/08/19

##### Registrant information

##### Name

NARGES HOSSEINI

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3700 2310

##### Email address

hoseinin941@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-04-05, 1397/01/16

##### Expected recruitment end date

2018-10-19, 1397/07/27

##### Actual recruitment start date

2018-04-05, 1397/01/16

##### Actual recruitment end date

2018-10-19, 1397/07/27

**Trial completion date**

2018-10-19, 1397/07/27

**Scientific title**

Effect of Withania somnifera Root Extract on Anxiety Symptoms in Children with Attention deficite and Hyperactivity Disorder

**Public title**

The effect of Withania somnifera on anxiety symptoms in children with ADHD

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Diagnosis of ADHD based on DSM-5 criteria aged 7-12 years Complete consent form by parent or guardian Normal IQ Symptoms of simultaneous anxiety

**Exclusion criteria:**

The patient's unwillingness to participating in the research project Systemic disease Interventional psychiatric illness intellectual disability

**Age**

From **7 years** old to **12 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

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

**Sample size**

Target sample size: **28**

Actual sample size reached: **28**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients are selected through available sampling. They are randomly divided into two groups of case and control according to the random numbers table.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

The study is double blind: the form of drug and placebo is the same, and the evaluator, the patient and the analyst are not aware of what treatment they are using, and drug intervention is identified by the pharmacist in sealed envelopes with a numeric code.

**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**

Ghoreishi Department, Daneshgah Ave, Mashhad

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9175845643

**Approval date**

2017-08-02, 1396/05/11

**Ethics committee reference number**

ir.mums.fm.rec.1396.214

## Health conditions studied

1

**Description of health condition studied**

Attention- Deficit Hyperactivity Disorders

**ICD-10 code**

F90

**ICD-10 code description**

Attention-deficit hyperactivity disorders

## Primary outcomes

1

**Description**

Anxiety symptoms in children with ADHD

**Timepoint**

At the beginning of STUDY and the week 3 and 6

**Method of measurement**

Child Anxiety Test based on the revised child anxiety scale(RCMA)

2

**Description**

Symptoms of ADHD

**Timepoint**

Weeks 3 and 6

**Method of measurement**

ADHD rating scale

## Secondary outcomes

empty

## Intervention groups

1

**Description**

Intervention group: Withania somnifera capsule is orally administered at a dose of 10 mg once daily for 6 weeks

### Category

Treatment - Drugs

## 2

### Description

Control group: The placebo capsule is similar to the Withania somnifera capsule orally at a dose of 10 mg once a day for 6 weeks.

### Category

Placebo

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Ebne-sina Hospital

#### Full name of responsible person

Fatemeh Moharary

#### Street address

Ebne-sina Hospital, Hoorre Ameli Street, Mashhad, Iran

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9195983134

#### Phone

+98 51 3700 2301

#### Email

Hoseinin941@mums.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Fatemeh Mohareri

#### Street address

Ebne-sina Research Center, Horre Ameli Street, Mashhad

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9195983134

#### Phone

+98 51 3711 2701

#### Email

Moharerif1@mums.ac.ir

#### 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

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

Fatemeh Mohareri

#### Position

Associate Professor

#### Latest degree

Subspecialist

#### Other areas of specialty/work

Psychiatrics

#### Street address

Ebne-sina hospital , Horre Ameli Avenue, Mashhad

#### City

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#### Province

Razavi Khorasan

#### Postal code

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#### Phone

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#### Email

Moharerif1@mums.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Fatemeh Mohareri

#### Position

Associate Professor

#### Latest degree

Subspecialist

#### Other areas of specialty/work

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**Email**

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**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Narges Hosseini

**Position**

Assistant Professor

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Psychiatrics

**Street address**

Horre-Ameli Blv

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9195983134

**Phone**

+98 51 3700 2301

**Email**

Hoseinin941@mums.ac.ir

**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**

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**

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

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

The total individual participants' data and the results of the study after the deidentification of the individuals are shared.

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

starting in April 2019

**To whom data/document is available**

All researchers are able to access the study results

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

Unidentifiable information is not shared with another organization

**From where data/document is obtainable**

Unidentifiable information is not available to applicants

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

Study data is published in the course of the paper and no other personal data is available to applicants

**Comments**