Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Effect of Withania somnifera Root Extract on Anxiety Symptoms in Children with Attention deficite 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 weeks3 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 Somnifra 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 somnifira 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

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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

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Person responsible for scientific inquiries

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Associate Professor

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Person responsible for updating data

Contact
Name of organization / entity
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Full name of responsible person
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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
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