Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

Evaluation of therapeutic effects of Neurosed syrup on the clinical symptoms of children with ADHD -A randomized double blind trial

Protocol summary

Study aim

Investigating the therapeutic effect of Neurosed syrup on the symptoms of attention deficit hyperactivity disorder (ADHD), investigating the possible side effects of using this drug.

Design

A double-blind, controlled, randomized, phase 3 clinical trial on 50 patients. A and B cards are used for randomization.

Settings and conduct

50 people from children with ADHD, referring to Imam Ali Clinic in Shahre-kord will be gradually included in the study using the available method. Using cards A and B, people are placed in two intervention or control groups. Neurosed syrup will be given to the intervention group and placebo to the control group. At this time, the symptoms related to ADHD disorder in these children are investigated using the Conners parent questionnaire, which is completed by the child's father or mother. After the completion of the one-month treatment period, the mentioned questionnaire is filled again by the parent. The changes in the obtained score are analyzed to check the effect of the drug. The doctor conducting the trial and the patient do not know the content of syrups A and B until the end of the study, so the study is double-blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children with ADHD, their age should be 5-12 years. Exclusion criteria: Use of Barbiturates, drugs that suppress the central nervous system, and blood sugar-lowering drugs, Presence of other concurrent diseases, not cooperating.

Intervention groups

The intervention group (25 people) will receive Neurosed syrup, which contains the active ingredient, once a day for one month. The control group (25 people) consumes the placebo that does not contain the active substance once a day for one month.

Main outcome variables

Symptoms of ADHD (changes in the scores obtained from the Connors parents' questionnaire before and after the intervention)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230718058834N1**
Registration date: **2023-11-21, 1402/08/30**
Registration timing: **prospective**

Last update: **2023-11-21, 1402/08/30**
Update count: **0**

Registration date

2023-11-21, 1402/08/30

Registrant information

Name

Maryam Torabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3668 1508

Email address

st-torabi@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-01, 1402/09/10

Expected recruitment end date

2024-01-30, 1402/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of therapeutic effects of Neurosed syrup on the clinical symptoms of children with ADHD -A randomized double blind trial

Public title
Effect of Neurosed syrup on ADHD

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Children with ADHD The age of people should be 5-12 years

Exclusion criteria:
Use of Barbiturates, drugs that suppress the central nervous system, and blood sugar-lowering drugs Presence of other concurrent diseases

Age
From **5 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: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be gradually included in the study according to the available method and will be assigned to two intervention and control groups based on the random allocation method. For this purpose, we place 50 cards with the letter A on 25 of them and the letter B on the other 25 in an envelope and randomly take out one card for each patient. The word that comes out shows the group of the patient.

Blinding (investigator's opinion)
Double blinded

Blinding description
In order to blind the patients, Norosed syrup and placebo are prepared from the same company and in the same packaging. The doctor conducting the trial and the patient do not know the content of the original syrups and placebo until the end of the study and extracting the results, so the study is double-blind.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of the School of Medicine, Shahrekord University of Medical Sciences

Street address
Headquarters of Shahrekord University of Medical Sciences,Kashani Street, Shahrekord, Chaharmahal va Bakhtiary, Iran

City
Shahr-e Kord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8815713471

Approval date
2023-06-10, 1402/03/20

Ethics committee reference number
IR.SKUMS.MED.REC.1402.012

Health conditions studied

1

Description of health condition studied
Attention Deficit Hyperactivity Disorder (ADHD)

ICD-10 code
F90.0

ICD-10 code description
Attention-deficit hyperactivity disorder, predominantly inattentive type

Primary outcomes

1

Description
ADHD score according to Conners parent questionnaire

Timepoint
Before the start of the intervention and one month after consuming Neurosed syrup

Method of measurement
Conners parent questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: A number of 25 children aged 5-12 years with ADHD referred to Imam Ali Shahrekord clinic,

who will use Neurosed syrup, which contains Melissa Officinalis extract and vitamins B and C, once a day for a month.This syrup is produced by Touba Faraz Pars company. Before and after the intervention, the symptoms related to ADHD disorder in these patients are examined using the Conners parents' questionnaire.

Category

Treatment - Drugs

2

Description

Control group: A number of 25 children aged 5-12 with ADHD referring to Imam Ali Shahrekord clinic who will use placebo syrup once a day for one month. This syrup is produced by Touba Faraz Pars Company and it is not different from the original syrup in terms of appearance but it does not contain the active ingredient. Before and after the intervention, the symptoms related to ADHD disorder in these patients are examined using the Conners parents' questionnaire.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam Ali clinic
Full name of responsible person
Elham Zarean
Street address
Shariati Blvd. Emam ali Clinic
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Elham Reisi
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Kashani street, Shahrekord, Chaharmahal va Bakhtiary, Iran
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahre-kord 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
Shahre-kord University of Medical Sciences
Full name of responsible person
Maryam Torabi
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Person responsible for updating data

Contact
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A Level or less
Other areas of specialty/work
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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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
To share the data and documents of this research, only the information related to the main outcome will be shared. Also, files that can be published and do not violate people's privacy will be published.
When the data will become available and for how long
The access period will start 6 months after the results are published.
To whom data/document is available
Our data will only be available to researchers working in academic and scientific institutions.
Under which criteria data/document could be used
Except for personal information about people, all of our data will be shared if certain requirements are met. Our data will only be used for comparable study and peer review by other researchers. Anyone working in universities or scientific institutions who wants to do similar study or confirm the accuracy of our data can access our data.
From where data/document is obtainable
All qualified individuals can collect data by referring to the project manager in order to acquire information. Contact information is available via email at torabimaryam75@gmail.com or the contact number 00989138653570.
What processes are involved for a request to access data/document
To receive information after sending the request, the requests will be reviewed within 10 days. If the above conditions are met, the information will be sent to the provided email within 30 days at most.
Comments