Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Efficacy evaluation of the Melissa officinalis syrup in treatment of children's anxiety symptoms with Attention Deficit Hyperactivity Disorder

Protocol summary

Study aim

Efficacy evaluation of the Melissa officinalis syrup in treatment of children's anxiety symptoms with ADHD

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 30 patients. Allocation Concealment method

Settings and conduct

The subjects of the research will be selected from ADHD sufferers, who referred to the pediatric psychiatric clinic in Ibn Sina Hospital in the second half of 1401. the intervention group will receive the syrup. The amount and safety of the above dose have been shown in previous studies and in the control group, in addition to the standard treatment, placebo syrup with a dose of 10 cc per day in two divided doses will be added to the standard medicine. The same color as herbal syrup is prepared in the same jars. At the beginning of the study and at 3 and 6 weeks, the patients were evaluated with the Attention Deficit Hyperactivity Disorder (ADHD-RS) and Revised Children's Manifest Anxiety Scale (RCMAS). The duration of the intervention in both groups is 6 weeks.

Participants/Inclusion and exclusion criteria

Patients suffering from ADHD disorder according to DSM V criteria, absence of other systemic and psychiatric disorders, IQ is within the normal range, their age is 7-12 years, and at least three months have passed since their standard drug treatment, and the informed consent form is completed Exclusion criteria: Patient refusal to continue treatment, occurrence of a systemic disease, initiation of new psychiatric treatment or new onset psychiatric disorder, drug side effects

Intervention groups

In addition to the standard treatment, the intervention group will be received dose of 0.2 cc per kilogram of weight The control group will be received a placebo syrup similar to herbal medicine

Main outcome variables

ADHD-RS scoring questionnaire The Revised Children's Manifest Anxiety Scale (RCMAS)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221001056065N1**
Registration date: **2022-11-07, 1401/08/16**
Registration timing: **registered_while_recruiting**

Last update: **2022-11-07, 1401/08/16**
Update count: **0**

Registration date

2022-11-07, 1401/08/16

Registrant information

Name

Maedeh Kamrani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3700 2202

Email address

kamranim@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-01, 1401/08/10

Expected recruitment end date

2023-04-30, 1402/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Efficacy evaluation of the Melissa officinalis syrup in treatment of children's anxiety symptoms with Attention Deficit Hyperactivity Disorder

Public title
Efficacy evaluation of the Melissa officinalis syrup in treatment of children's anxiety symptoms with Attention Deficit Hyperactivity Disorder

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
The patient with DSM V ADHD criteria, Absence of other systemic or psychiatric disorders, IQ in the normal range at least three months have passed since their standard drug treatment, Completion of the informed consent form by the parent
Exclusion criteria:

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

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization using https://www.sealedenvelope.com Allocation Concealment method: To ensure equal number of study subjects in two groups, permutation block method was used. For this purpose, we will use the website www.sealedenvelope.com in such a way that the number of 8 blocks of 4 members will be randomly created through the above site.

Blinding (investigator's opinion)
Double blinded

Blinding description
Sealed envelopes

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
School of Medicine, Mashhad University of Medical Sciences
Street address
Horameli St., Ibn Sina Hospital
City
Mashhad
Province
Razavi Khorasan
Postal code
919583134

Approval date
2022-07-26, 1401/05/04

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1401.285

Health conditions studied

1

Description of health condition studied
Attention Deficit Hyperactivity Disorder

ICD-10 code
F90.0

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

Primary outcomes

1

Description
Revised Children's Anxiety Scale

Timepoint
in 3 and 6 weeks

Method of measurement
The amount of change in the revised children's anxiety scale questionnaire

2

Description
Attention deficit hyperactivity disorder scoring scale questionnaires

Timepoint
in 3 and 6 weeks

Method of measurement
The amount of change in attention deficit hyperactivity disorder scoring scale

Secondary outcomes

1

Description

Revised Children's Manifest Anxiety Scale score

Timepoint

week 3 and 6

Method of measurement

The amount of change in the anxiety score

Intervention groups

1

Description

Intervention group: Melissa officinalis syrup of Ehyateb Daru Tabiat company with a dose of 0.2 cc per kilogram of weight in two divided doses recipients

Category

Treatment - Drugs

2

Description

Control group: Placebo syrup with a dose of 10 cc per day in two doses recipients

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ibn Sina Hospital

Full name of responsible person

Mojtaba Rezaee

Street address

Hor Ameli Street, Ibn Sina Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Ghayour Mobarhan

Street address

Mashhad, University Street, Beside Hoveyzeh Cinema, Qurashi Building, Research and Technology Vice, Chancellor

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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

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 Moharari

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Mojtaba Rezaee

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Psychiatry resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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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

After completing the study and obtaining permission from the Research Vice-Chancellor of Mashhad University of Medical Sciences, the researchers are ready to publish the results of the study in the form of an article.

When the data will become available and for how long

After the completion of the project (about one year after starting the work) and the resident's defense of his/her thesis, the researchers are ready to publish the results.

To whom data/document is available

Officials of Mashhad University of Medical Sciences and, therapists working in the field of mental health

Under which criteria data/document could be used

For the purpose of clinical use of the obtained results in the treatment of patients and in the event of the absence of clinical complications during the research

From where data/document is obtainable

Mashhad University of Medical Sciences, Research department

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

Refer to research unit of Mashhad Medical Sciences Faculty, Dissertations Unit and obtain access permission

Comments