Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Study of the effectiveness of Melissa officinalis extract on the treatment of children with attention deficit hyperactivity disorder

Protocol summary

Study aim
Study of effectiveness of alcoholic extract of Melissa officinalis on attention deficit hyperactivity disorder(ADHD) in children

Design
Two Side Blinded Randomised Trial

Settings and conduct
The location was Dr.Iraj Vosough, Parastar 1.2, Mashhad. Children from 6 to 15 with attention deficit hyperactivity disorder (ADHD) were chosen by specialists. This was a double blinded clinical trial. The content of capsules were unknown to both the doctor and patients, just pharmacist knew which group was drug or placebo. Capsules were given under name of group A and group B. Alcoholic extract of Melissa officinalis with a dose of 160 mg twice daily for 8 weeks was given to one group and placebo to another group under the same condition.

Participants/Inclusion and exclusion criteria
1.Dignosis of attention deficit hyperactivity disorder(ADHD) based on the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition(DSM-V) 2.children aged from 6 to 15 years old 3.Filling the consent form

Intervention groups
Patients were randomly divided into two groups. Both groups were given capsules with the same appearance. One group was treated with alcoholic extract of Melissa officinalis with a dose of 160 mg twice daily for 8 weeks and placebo was given to the control group twice daily for 8 weeks.

Main outcome variables
Attention Deficit Hyperactivity Disorder (ADHD)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190330043139N1**
Registration date: **2020-05-01, 1399/02/12**
Registration timing: **retrospective**

Last update: **2020-05-01, 1399/02/12**
Update count: **0**

Registration date
2020-05-01, 1399/02/12

Registrant information

Name
Pooria Vosouq

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3879 6373

Email address
v.pooria@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-12-22, 1397/10/01

Expected recruitment end date
2019-02-04, 1397/11/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Study of the effectiveness of Melissa officinalis extract on the treatment of children with attention deficit hyperactivity disorder

Public title
The effect of Melissa officinalis on the treatment of

children with attention deficit hyperactivity disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children aged 6-15 years old Diagnosis of Attention deficit hyperactivity disorder(ADHD) based on Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition(DSM-V) Filling the consent form

Exclusion criteria:

Age

From **6 years** old to **15 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The study is double blinded, the form of medication and placebo is the same and neither the patients nor the experimenters know who is receiving a particular treatment.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study patients, the doctor, experimenter and analisor have been kept blinded.

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 Science

Street address

Pharmacy Campus, Mashhad Medical University, Azadi Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9188617871

Approval date

2018-04-11, 1397/01/22

Ethics committee reference number

IR.MUMS.fm.REC.1396.556

Health conditions studied

1

Description of health condition studied

Attention deficit hyperactivity disorder

ICD-10 code

F90

ICD-10 code description

Attention-deficit hyperactivity disorders

Primary outcomes

1

Description

Patients with Attention deficit hyperactivity disorder (ADHD)

Timepoint

Before starting the study and at 0, 4, and 8 weeks after starting treatment

Method of measurement

Integrated visual Auditory(IVA)- Conners-Clinical Q-Quantitative Electroencephalography (qEEG) tests

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Placebo with a dose of 160 mg twice daily for 8 weeks

Category

Placebo

2

Description

Intervention group: Alcoholic extract of Melissa officinalis with a dose of 160 mg twice daily for 8 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Iraj Vosughs Office

Full name of responsible person

Dr. Iraj Vosugh
Street address
No.2.2, Parastar1.2 Ave, Ahmadabad
City
Mashhad
Province
Razavi Khorasan
Postal code
9176696561
Phone
+98 51 3844 9091
Email
v.pooria@yahoo.com
Web page address
http://www.drvosough.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Amir Houshang Mohammadpour
Street address
Pharmacy Campus, Mashhad Medical University, Azadi Square
City
Mashhad
Province
Razavi Khorasan
Postal code
17871 91886
Phone
+98 51 3844 9091
Email
V.pooria@yahoo.com
Web page address
http://pharmacy.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
Dr.Amir Houshang Mohammadpour
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Pharmacy Campus, Mashhad Medical University, Azadi Square
City
Mashhad
Province
Razavi Khorasan
Postal code
17871 91886
Phone
+98 51331801
Email
V.pooria@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Pooria Vosough
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
Medical Pharmacy
Street address
Pharmacy Campus, Mashhad Medical University, Azadi Square
City
Mashhad
Province
Razavi Khorasan
Postal code
17871 91886
Phone
+98 51331801
Email
V.pooria@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Pooria Vosough
Position
Student
Latest degree

Subspecialist

Other areas of specialty/work

Medical Pharmacy

Street address

Pharmacy Campus, Mashhad Medical University, Azadi Square

City

Mashhad

Province

Razavi Khorasan

Postal code

17871 91886

Phone

+98 51331801

Email

V.pooria@yahoo.com

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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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