

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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 Vosough  
**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  
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+98 51331801  
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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