

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Evaluation the efficacy of a syrup of *Echium amoenum*-*Melissa officinalis* in treatment of adolescents with Obsessive-Compulsive Disorder

Protocol summary

Study aim

Evaluation the efficacy of a syrup of *Echium Amoenum*-*Melissa Officinalis* in treatment of adolescents with Obsessive-Compulsive Disorder

Design

Randomized clinical trial, including intervention and control groups with parallel groups, double-blind The random allocation sequence using the random number table is www.randomization.com. The method of allocation concealment: indoor envelopes. The sample size is 20 people in each group.

Settings and conduct

Recruitment center: Child Psychaitry clinic at Ibn-e-Sina hospital Patients are evaluated by pediatric psychiatrist with Yale Brown Obsessive-Compulsive questionnaire in children and divided into intervention and control groups by simple randomization method. Patients and outcome assessors are unaware of the individuals assigned to the groups. The Yale Brown Obsessive-Compulsive questionnaire for Children is administered in week 4 and 8 of the study and questionnaires of quality of life, Anxiety, and Depression are completed at the beginning and end of the study for patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Obsessive-Compulsive Disorder with a diagnosis of pediatric psychiatry according to DSM-5 criteria; Ages 13 to 17 years Exclusion criteria: Psychosis; Bipolar disorder; Catatonic symptoms; Drug abuse; Severe or debilitating illnesses; Phenobarbital consumption; Oxazepam consumption; Sedative drugs consumption

Intervention groups

Intervention group will receive a herbal syrup, 0.3 milliliter per kilogram of body weight and 50 mg Fluvoxamine tablets daily and the control group will receive placebo syrup and 50 mg Fluvoxamine tablets daily for 8 weeks.

Main outcome variables

Obsessive score on children's Yale-Brown Obsessive

Compulsive questionnaire

General information

Reason for update

Need to limit the target group to adolescents to standardize the dose of the drug; Inclusion of all adolescents with obsessive-compulsive disorder (of varying severity) in the study

Acronym

IRCT registration information

IRCT registration number: **IRCT20191127045521N1**

Registration date: **2019-12-05, 1398/09/14**

Registration timing: **prospective**

Last update: **2021-05-12, 1400/02/22**

Update count: **1**

Registration date

2019-12-05, 1398/09/14

Registrant information

Name

Maryam Hosseini Abrishami

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

2020-01-21, 1398/11/01
Actual recruitment end date
2021-01-27, 1399/11/08
Trial completion date
2021-03-25, 1400/01/05

Scientific title

Evaluation the efficacy of a syrup of Echium amoenum-Melissa officinalis in treatment of adolescents with Obsessive-Compulsive Disorder

Public title

Evaluation the efficacy of a syrup of Echium amoenum-Melissa officinalis in treatment of adolescents with Obsessive-Compulsive Disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Obsessive-Compulsive Disorder with a diagnosis of pediatric psychiatry according to DSM-5 criteria Ages 13 to 17 years

Exclusion criteria:

Psychosis Bipolar disorder Catatonic symptoms Drug abuse Severe or debilitating illnesses Phenobarbital consumption Oxazepam consumption Sedative drugs consumption

Age

From **13 years** old to **17 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into Intervention and control groups using simple randomization (www.randomization.com). How to hide the allocation is with closed envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients in this study are unaware that they are assigned to a control or intervention group. Intervention group will receive Echium amoenum-Melissa officinalis syrup and fluoxetine tablets. Control group will receive placebo and fluoxetine tablets. The outcome assessor is also unaware of which group the patient belongs to.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of Mashhad University of Medical Sciences

Street address

Mashhad University Of Medical Sciences, University Street

City

Mashhad

Province

Razavi Khorasan

Postal code

13944-91388

Approval date

2019-09-21, 1398/06/30

Ethics committee reference number

IR.MUMS.REC.1398.221

Health conditions studied

1

Description of health condition studied

Obsessive-Compulsive Disorder

ICD-10 code

F42.2

ICD-10 code description

Mixed obsessional thoughts and acts

Primary outcomes

1

Description

Obsessive score on children's Yale-Brown Obsessive Compulsive questionnaire

Timepoint

pretest, 4 weeks after beginning, post-test (at the end of 8 weeks)

Method of measurement

children's Yale-Brown Obsessive Compulsive questionnaire

Secondary outcomes

1

Description

Quality of life score

Timepoint

pretest, post-test (at the end of 8 weeks)

Method of measurement

The World Health Organization Quality of Life Questionnaire

2

Description

Anxiety score

Timepoint

pretest, 4 weeks after beginning, post-test (at the end of 8 weeks)

Method of measurement

Spence Children's Anxiety Questionnaire

3

Description

Depression score

Timepoint

pretest, 4 weeks after beginning, post-test (at the end of 8 weeks)

Method of measurement

Maria Kovas Depression Questionnaire

Intervention groups

1

Description

Intervention group will receive a Echium amoenum-Melissa officinalis syrup, 0.3 milliliter per kilogram of body weight and 50 mg Fluvoxamine tablets daily for 8 weeks.

Category

Treatment - Drugs

2

Description

Control group will receive placebo syrup and 50 mg Fluvoxamine tablets daily for 8 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Child Psychaitry clinic at Ibn-e-Sina hospital

Full name of responsible person

Dr. Atefeh Soltanifar

Street address

Ibn-e-Sina psychiatric Hospital, Horre ameli avenue, Boo Ali square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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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

Maryam Hosseini Abrishami

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

School of Traditional and Compelementary Medicine,

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Person responsible for scientific inquiries

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Ph.D.

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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

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