Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Feb 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 fluoxamine tablets. Control group will receive placebo and fluoxamine 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 Univercity 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
Street address
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Web page address
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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
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Person responsible for updating data

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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