Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Nov 2026

Dextromethorphan augmentation therapy for moderate-to-severe obsessive–compulsive disorder: randomized, double-blind,placebo-controlled trial

Protocol summary

Study aim
Effect of dextromethorphan as an augmentation therapy in obsessive-compulsive disorder patients without adequate response to drug treatment

Design
randomized, blinded, controlled clinical trial with a parallel group design of 54 patients.Randomization with binomial distribution

Settings and conduct
A number of 54 patients are selected from the patients who meet the conditions for entering the study. Before the start of the study, the statistician selects the patients by randomization for two groups A and B. Dextromethorphan drug And the placebo is placed in the same boxes with the code and given to the patients based on the codes.The patient, clinician, researcher, and data analyst will be blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria include patients over 18 years of age who have been diagnosed with moderate-to-high obsessive-compulsive disorder (YBOCS>16) and have not responded to 12 weeks of obsessive-compulsive disorder treatment with an adequate dose of an SSRI drug, and also filled out an informed consent form; The conditions of non-entry include patients who have comorbidity with other psychiatric disorders except major depressive disorder, such as psychotic disorders, drug-related disorders, and also have severe kidney and liver disease, unstable medical conditions, or pregnancy ,are is.

Intervention groups
In the intervention group, one tablet of dextromethorphan with a dose of 15 mg BID daily is given orally along with the previously used SSRI drug for 90 days from Dana Pharmaceutical Company. In the control group, similar tablets, which is prepared by the pharmacy of Shahid Dr. Beheshti Hospital,is given orally BID daily along with the previously used SSRI drug for 90 days.

Main outcome variables
Severity of Obsessive Compulsive Disorder based on Obsessive Compulsive Scale (Y-BOCS)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221227056943N1**
Registration date: **2023-01-16, 1401/10/26**
Registration timing: **prospective**

Last update: **2023-01-16, 1401/10/26**
Update count: **0**

Registration date
2023-01-16, 1401/10/26

Registrant information

Name
Romina Bagheri

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 28 3336 8142

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-20, 1401/10/30

Expected recruitment end date
2023-06-10, 1402/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Dextromethorphan augmentation therapy for moderate-to-severe obsessive–compulsive disorder: randomized, double-blind,placebo-controlled trial

Public title

Dextromethorphan augmentation therapy for obsessive compulsive disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients diagnosed with obsessive-compulsive disorder with moderate to high severity (YBOCS>16) Patients who have not responded to 12 weeks of obsessive-compulsive disorder treatment with an adequate dose of an SSRI People over 18 years old People who have filled out informed consent

Exclusion criteria:

Comorbidity with other psychiatric disorders except major depressive disorder, including psychotic disorders, substance dependence disorders Pregnancy Severe kidney and liver disease Unstable medical condition

Age

From **18 years** old

Gender

Both

Phase

4

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to assign patients to two intervention and control groups, before the start of the study, the statistician determines the treatment group of the patients in the order of entering the study by generating random data with a binomial distribution with a probability of 0.5, and the patients are divided into two groups in the order of entering the study. A and B are entered. In this way, the researcher has no involvement in allocating the type of treatment. The outcome assessor and the clinician will not be aware of the randomization procedure.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to assign patients to two intervention and control groups, before the start of the study, the statistician determines the treatment group of the patients in the order of entering the study by generating random data with a binomial distribution with a probability of 0.5, and the patients are divided into two groups in the order of entering the study. A and B are entered. According to the number of patients studied, dextromethorphan and placebo drugs, which are completely similar in terms of shape and size, are placed in similar boxes and the boxes are coded. Codes related to the drug and the placebo will be done by someone other than the researcher and clinician, and the patient, clinical caregiver, researcher, data collector, and data analyst will not know about it. will be given to patients.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zanjan University of Medical Sciences

Street address

Dr. Behshti Hospital,Arg Sq,Besat street,North Sadi

City

Zanjan

Province

Zanjan

Postal code

4513615788

Approval date

2022-11-22, 1401/09/01

Ethics committee reference number

IR.ZUMS.REC.1401.236

Health conditions studied

1

Description of health condition studied

obsessive compulsive disorder

ICD-10 code

F42

ICD-10 code description

Obsessive-compulsive disorder

Primary outcomes

1

Description

Severity of Obsessive Compulsive Disorder based on the

Yale-Brown Obsessive Compulsive Scale (Y-BOCS)

Timepoint

Yale-Brown obsessive compulsive scale (Y-BOCS) was measured at the beginning of the study and 30 and 90 days after the start of treatment

Method of measurement

Yale-Brown obsessive compulsive scale (Y-BOCS) Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: one tablet of dextromethorphan with a dose of 15 mg BID daily are given orally along with the previously used SSRI drug for 90 days from Dana Pharmaceutical Company.

Category

Treatment - Drugs

2

Description

Control group:One pill is given orally BID daily along with the previously used SSRI drug for 90 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Dr Beheshti hospital

Full name of responsible person
Romina Bagheri

Street address
Shahid Dr.Beheshti hospital,Arg Sq,Besat street,North Sadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Zanjan 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
Zanjan University of Medical Sciences

Full name of responsible person
Romina Bagheri

Position
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
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
Title and more details about the data/document
Data may be published after de-identifying individuals.
When the data will become available and for how long
When publishing the results
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
For scientific research
From where data/document is obtainable
Library of Zanjan University of Medical Sciences
What processes are involved for a request to access data/document
Refer to the university library
Comments