

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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)

Phone

+98 28 3336 8142

Email address

romina.bagheri.s@gmail.com

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

City

Zanjan

Province

Zanjan

Postal code

4513615788

Phone

+98 24 3354 4001

Email

beheshti@zums.ac.ir

Web page address

<https://beheshti.zums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Samad Nedri

Street address

Zanjan University of Medical Sciences,Azadi Blvd

City

Zanjan

Province

Zanjan

Postal code

۴۵۱۵۶۱۳۱۹۱

Phone

+98 24 3315 6141

Fax

+98 24 3342 0460

Email

research@zums.ac.ir

Web page address

<https://research.zums.ac.ir/>

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

Street address

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

City

Zanjan

Province

Zanjan

Postal code

4513615788

Phone
+98 28 3336 8142
Fax
Email
Romina.bagheri.s@gmail.com

Person responsible for scientific 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
Street address
Dr. Behshti Hospital, Arg Sq, Besat street, North Sadi
City
Zanjan
Province
Zanjan
Postal code
4513615788
Phone
+98 28 3336 8142
Fax
Email
Romina.bagheri.s@gmail.com

Person responsible for updating data

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

City
Zanjan
Province
Zanjan
Postal code
4513615788
Phone
+98 28 3336 8142
Fax
Email
Romina.bagheri.s@gmail.com

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