Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

The effect of dextromethorphan on the severity of symptoms in patients with resistant obsessive-compulsive disorder: A triple blinded, randomized clinical trial

Protocol summary

Study aim
Comparison of the effects of dextromethorphan (60 mg / day) against placebo on the severity of symptoms by measuring the Yale-Brown Obsseive-Compulsive Scale in patients with obsessive-compulsive disorder

Design
A randomized clinical trial, on 48 patients, block randomization (via randomization site), parallel groups, triple-blind, phase 2.

Settings and conduct
This is a randomized triple-blind study.This study had been performed on 48 patients with obsessive-compulsive disorder, who had been referred to outpatient clinical of EbneSina Hospital. Patients had been evaluated separately by a psychiatrist. The severity of obsessive-compulsive disorder in these patients had been assessed at the beginning of the study by interviewing a psychiatrist using the Yale Brown Obsessive-Compulsive Disorder (Y-BOCS) scale , who met the inclusion and exclusion criteria, was enter the study after obtaining informed consent.The results of the psychiatrist's interview with the patient and the evaluation of (Y-BOCS) scale had been recorded in a special questionnaire for each patient at the beginning of the study (before the intervention) and 1 month, 2 months and 3 months after the intervention.

Participants/Inclusion and exclusion criteria
1)OCD patients who have been treated with high doses of SSRI for at least 8 weeks but have a Y-BOCS index score higher than 10. (High doses of SSRI include: Sertraline 200mg/day, Paroxetine 60mg/day, Fluoxetine 80mg/day and Fluvoxamine mg/day) 2)subjects aged 18 to 60 years 3) Obtaining the patient's informed consent

Intervention groups
group1: high dose of SSRI + placebo group. group2: high dose of SSRI + dextromethorphan (60 mg/day) group3: high dose of SSRI + memantine (20 mg/day)

Main outcome variables
(Y-BOCS) YALE-BROWN OBSESSIVE COMPULSIVE SCALE

General information

Reason for update
patients intolerance

Acronym

IRCT registration information
IRCT registration number: **IRCT20120520009801N6**
Registration date: **2021-11-02, 1400/08/11**
Registration timing: **prospective**

Last update: **2026-02-04, 1404/11/15**
Update count: **2**

Registration date
2021-11-02, 1400/08/11

Registrant information

Name
Amir Hooshang Mohammadpour

Name of organization / entity
Mashhad University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-19, 1401/01/30

Expected recruitment end date
2024-02-19, 1402/11/30

Actual recruitment start date

2022-08-23, 1401/06/01

Actual recruitment end date

2024-11-20, 1403/08/30

Trial completion date

2024-11-20, 1403/08/30

Scientific title

The effect of dextromethorphan on the severity of symptoms in patients with resistant obsessive-compulsive disorder: A triple blinded, randomized clinical trial

Public title

The effect of dextromethorphan on the severity of symptoms in patients with resistant OCD

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

OCD patients who have been treated with high doses of SSRI for at least 8 weeks but have a Y-BOCS index score higher than 10. (High doses of SSRI includ: Sertraline 200mg/day, Paroxetine 60mg/day, Fluoxetine 80mg/day and Fluvoxamine mg/day) subjects aged 18 to 60 years Obtaining the patient's informed consent

Exclusion criteria:

Pregnancy or breastfeeding Using serotonergic drugs other than SSRIs Use of NMDA receptor antagonists other than dextromethorphan and memantine Psychotic and bipolar disorders (based on DSM-5 criteria) past medical history of Liver dysfunction (LFT> 3ULN) past medical history of Kidney dysfunction (GFR <60 ml / kg / min) past medical history of Thyroid Disorders History of seizures

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **75**

Actual sample size reached: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

To facilitate the random assignment of individuals to study groups, a permutation block method was employed, utilizing blocks of sizes 3 and 6. Randomization and allocation concealment were performed in accordance with CONSORT recommendations. A computer-generated randomization list was created using a web-based randomization service www.sealedenvelope.com, which was prepared by an independent statistician not involved in patient recruitment or outcome assessment. Based on this list, study medications were packaged into identical, opaque, sequentially numbered boxes corresponding to allocation codes A, B, and C. The boxes were indistinguishable in external appearance, and only the code number was visible to the recruiting clinicians. At the time of enrollment, each participant received the next available box in numerical order, ensuring that the treatment assignment remained concealed from investigators and participants until the end of the study or until unblinding was required for safety reasons

Blinding (investigator's opinion)

Triple blinded

Blinding description

As our data are collected step by step and patients are gradually included in the study, concerning the time of inclusion and at the beginning of inclusion according to the sequence obtained in the randomization stage, after evaluating inclusion criteria, the patients will be assigned to either control groups or interventions groups by physician. These codes are provided to the physician's office. It is worth mentioning that clinical pharmacy should be fully aware of the type of code. The clinical pharmacist is also provided with the medications in terms of the assigned number (C or B or A) and is fully aware of the fact that which medication is Dextromethorphan or Memantine or placebo, as well. (This clinical pharmacist is engaged neither in prescribing and evaluating the treatments, nor in analyzing data, and is exclusively responsible for maintaining codes and delivering medications to the patients based on a random code allocated by the physician.) The assigned code is recorded in the CRF form. After taking either the medication or placebo for three months by the patients, in the clinic of Ebn-e-Sina Hospital, the patients are appraised by a physician who has no idea which drug the patients have received and is only aware of the assigned codes and then carries out the appropriate evaluations. After documentation, the results in the form of codes are provided to the person who performs the data analysis. The data analysis is performed while the data analyzer has no information about the type of the taken medication, and all confidential information is recorded and stored without mentioning the patient's name

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

Street address

Ethic committee of Mashhad University of Medical

Sciences, Ghoreishi building, Daneshgah street

City
Mashhad

Province
Razavi Khorasan

Postal code
91375-345

Approval date
2021-10-23, 1400/08/01

Ethics committee reference number
IR.MUMS.REC.1400.221

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
Evaluation of the effect of dextromethorphan in comparison with placebo on reducing the severity of symptoms in patients with obsessive-compulsive disorder based on (Y-BOCS) YALE-BROWN OBSESSIVE COMPULSIVE SCALE.

Timepoint
Before intervention and 1 month, 2 months and 3 months after intervention.

Method of measurement
Yale–Brown Obsessive Compulsive Scale

Secondary outcomes

1

Description
Comparison of changes in executive functions in different groups

Timepoint
Before intervention and 3 months after intervention

Method of measurement
Delis-Kaplan Executive Function System (D-KEFS) tests

2

Description
adverse effect of drugs

Timepoint
In the first, second, and third months of using the medication, and whenever the patient experienced a complication, there was the possibility of contacting the clinical pharmacist who was aware of the types of codes.(However, she did not participate in any of the randomization, drug administration, or data analysis processes.)

Method of measurement
patients declaration

Intervention groups

1

Description
Patients are selected from outpatients who visit the clinic of EbneSina Hospital. In the intervention group, patients diagnosed with obsessive-compulsive disorder, who meet the inclusion and exclusion criteria, will randomly add one of the following 3 interventions to their high-dose (SSRI) regimen. (This study will be performed on patients with obsessive-compulsive disorder who have been on high doses of SSRI for at least 8 weeks but have a Y-BOCS index score higher than 10) The severity of symptoms of obsessive-compulsive disorder will be assessed using the Yale Brown Obsessive-Compulsive Disorder Scale before intervention and 1 month, 2 months and 3 months after intervention. The Delis-Kaplan Executive Performance Test (D-KEFS) will be evaluated before the intervention and 3 months after the intervention. adverse effect was evaluated through study and each month of drug consumption. Intervention group1: high dose of SSRI + dextromethorphan (60 mg/day) (High doses of SSRIs include sertraline: maximum 200mg / day, paroxetine: maximum 60mg / day, fluoxetine: maximum 80mg / day, fluvoxamine: maximum 300mg / day) The main medication, Dextromethorphan, is purchased from Pursina pharmaceutical company.

Category
Treatment - Drugs

2

Description
Intervention group: high dose of SSRI + memantine (20 mg/day) (High doses of SSRIs include sertraline: maximum 200mg / day, paroxetine: maximum 60mg / day, fluoxetine: maximum 80mg / day, fluvoxamine: maximum 300mg / day)

Category
Treatment - Drugs

3

Description
third group: high dose of SSRI + placebo The placebo tablet contains all the ingredients of the main pill and only lacks the active ingredient dextromethorphan and memantine, and will receive 1 tablets a day for 3 months in addition to the standard treatment regimen for obsessive-compulsive patients. The placebo tablet, which is similar to the main medication in terms of shape and color is made in Mashhad School of Pharmacy in accordance with the principles of GLP.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ebn'e Sina Hospital, outpatient clinic
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
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Full name of responsible person
Mohammadpour Amir Hooshang
Position
Professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
all collected deidentified IPD
When the data will become available and for how long
starting 6 months after publication
To whom data/document is available
only available for people working in academic institutions
Under which criteria data/document could be used
only available for people working in academic institutions and there is not another condition
From where data/document is obtainable
mohamadpoorah@mums.ac.ir
What processes are involved for a request to access data/document
mohamadpoorah@mums.ac.ir
Comments