Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of Ondansetron augmentation in tretment resistant obsessive-copulsive disorder

Protocol summary

Study aim

The study of the effect of ondansetron on the treatment of resistant obsessive compulsive disorder

Design

This is a two-blind clinical trial that will be conducted in Kashan University of Medical Sciences for 12 weeks in 1396. Cases will select from patients diagnosed by psychiatrist who meet DSM-5 criteria referring to psychiatric clinics affiliated to Kashan university of medical scinces .These patient will divide to two groups of 20 people

Settings and conduct

This is a two-blind clinical trial that will be conducted in Kashan University of Medical Sciences for 12 weeks in 1396.Creation,on the one hand ,is the lack knowledge of the psychiatrist of the distrbution of drugs between the patients,and the blind side of patient who has no information about the type of drug used. Dispensing will done by a psychiatric nurse and the psychiatrist. The facilitator will only examine the patients on the Yale Brown Scale. This study will take long about 3 months.

Participants/Inclusion and exclusion criteria

1. Aged 18 years and over. 2. Despite received at least three months of adequate and tolerable SSRI drugs, the scores of obsessive-compulsive scores 16 and up. 3. No pregnancy or breastfeeding in women. 4. No psychiatric disorder such as Bipolar in the axis 1 of psychiatry. 5. Lack of mental retardation in the axis 2 of psychiatry. 6. Lack of alcohol intake 6 months before the study. 7. Lack of physical disease that prevents the ondansetron release. 8. Lack of psychotherapy during the study; Exit of study: 1. Acute and severe physical illness during the study. 2. Non-follow-up for 4 weeks. 3. Severe complications during treatment.4 not using contraceptive methods in females

Intervention groups

Patients will divided into two groups. The first group will receive SSRI and ondansetrone at a dose of 8 mg daily and the other will receive SSRI and placebo.T

Main outcome variables

1- Determination of demographic characteristics of patients participating in the study - 2- Determine the median of the score - Y-BOCS in the two groups in the week zero. Fourth. Eighth and twelfth 3- Comparison of the mean score of Y-BOCS in two groups at week zero. Fourth. Eighth and twelfth 4- Comparison of mean scores - Y = BOCS in the group receiving ondansetron and placebo in terms of confounding variables By gender. The drug is consumed during the period of illness and the age of the onset of the disease 5- Determine the response rate to treatment in the two groups in the fourth week. Eighth and -Twelve 6- Comparison of the response rate to treatment in the two groups in the fourth week. Eighth and Twelve

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170723035247N1**
Registration date: **2018-01-03, 1396/10/13**
Registration timing: **retrospective**

Last update: **2018-01-03, 1396/10/13**
Update count: **0**

Registration date

2018-01-03, 1396/10/13

Registrant information

Name

Mehdi Adel

Name of organization / entity

Kashan University of Medical Scinence

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 9111

Email address

adel-m@kaums.ac.ir

Recruitment status
Recruitment complete
Funding source
Kashan University of Medical Science

Expected recruitment start date
2017-06-22, 1396/04/01
Expected recruitment end date
2017-08-23, 1396/06/01
Actual recruitment start date
2017-06-21, 1396/03/31
Actual recruitment end date
2017-08-22, 1396/05/31
Trial completion date
empty

Scientific title
The effect of Ondansetron augmentation in tretment resistant obsessive-copulsive disorder

Public title
The effect of Ondansetron to tretment obsessive - copmpulsive disorder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Aged 18 years and over. Despite received at least three months of adequate and tolerable SSRI drugs, the scores of obsessive-compulsive scores 16 and up. No pregnancy or breastfeeding in women. No psychiatric disorder such as Bipolar in the axis 1 of psychiatry. Lack of mental retardation in the axis 2 of psychiatry. Lack of alcohol intake 6 months before the study. Lack of psychotherapy during the study.
Exclusion criteria:
Acute and severe physical illness during the study. Non-follow-up for 4 weeks. Severe complications during treatment. Not using contraceptive methods in females
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data and Safety Monitoring Board

Sample size
Target sample size: **40**
Actual sample size reached: **40**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Blindness on the one hand is the lack of knowledge of the distributor's psychiatrist about the distribution of drugs among the patients, and the blind on the other side, which patients do not know the type of drug (ondansetron or placebo). The distribution of the medicine will be done by the nurse and the psychiatrist will examine the patients in terms of the scale of Yale-Brown
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Kashan University of Medical Sciences ethic commetee in health sciences
Street address
Medical college, Ghotb Ravandi boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
8715973446
Approval date
2016-09-27, 1395/07/06
Ethics committee reference number
IR.KAUMS.REC.1395.66

Health conditions studied

1

Description of health condition studied
Obsessive -compulsive disorder
ICD-10 code
F42
ICD-10 code description
F42-The essential feature is recurrent obsessional thoughts or compulsive acts.obsessional thoughts are ideas,images,or impuses that enter the patients mind again and again in stereotyped form.They are , almost invariably distressing and the patient ofte

Primary outcomes

1

Description
Severity obsessive compulsion
Timepoint

Before the start of trial and every four weeks

Method of measurement

Yale Brown Obsessive -Compulsion Scala

Secondary outcomes

1

Description

Sudden drug effect

Timepoint

Before the start of the trial ,the end of the first-two-fourth-sixth-eighth-twelfth weeks

Method of measurement

Interviwe and examination

Intervention groups

1

Description

In the first intervention group: In addition to SSRIs, it is given ondansetron at an average dose of 8 mg per day for 2 weeks.

Category

Treatment - Drugs

2

Description

In the control group, with SSRIs, the patient will receive the same dose of placebo for 12 weeks as the original drug.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Psychiatric Clinics of Kashan University of Medical Science

Full name of responsible person

zahra Sepehrmanesh MD

Street address

Ghotbe ravandi Blv. Kargarnejad hospital

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Email

z.sepehrmanesh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for resaerch Kashan University of Medical Sciences

Full name of responsible person

Dr Gholam Ali Hamidi

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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

Vice chancellor for resaerch Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Zahra sepehrmanesh MD

Position

Assistant professor of child and adolescent psychiatry

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Full name of responsible person
Zahra Sepehrmanesh MD
Position
Assistant professor of child and adolescent psychiatry
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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Mehdi Adel MD
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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