Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of Aripiprazole augmentation of Sertraline in adolescents with obsessive-compulsive disorder

Protocol summary

Study aim

Determine the combined effect of Aripiprazole and Sertraline in the treatment of obsessive-compulsive disorder in adolescents

Design

From the patients referred by the psychiatric colleagues, allocation of type of treatment is done randomly.Due to gradual referral of patients and to maintain balance in groups, permuted block randomization is used that at any moment the difference in the number of samples in each group is less than 2-4. (Blocks 4 and 6). Both treatments are provided in the same coverage that the presenter and the patients will be blind to.

Settings and conduct

Patients are checked in at eight times. The first method is to randomize and receive the drug-free drug at the end of the first and second weeks, and then every two weeks until the end of the study, which will be the 12th week. During the fourth, eighth, and twelfth weekly visits, referral of patients to a psychiatrist Collaborator, the score of Yale Brown scale will be measured. The response to treatment by changing the scale of the scale from the baseline to the end of the study and the comparison between the two drugs is considered. Both treatments are provided in the same cover that the presenter and the patients They will be blind to it.

Participants/Inclusion and exclusion criteria

Obsessive compulsive disorder adolescents referring to psychiatric clinics in Kashan, by psychiatrist based on DSM 5

Intervention groups

In this study, the patients were randomly assigned to two groups with obsessive-compulsive disorder with a score of Yale Brown's questionnaire fitted to this age group above 16. In one group of Sertraline and placebo, and in the other group, Sertraline is co-administered with Aripiprazole.

Main outcome variables

Study of therapeutic effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190104042227N1**
Registration date: **2019-01-25, 1397/11/05**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-25, 1397/11/05**
Update count: **0**

Registration date

2019-01-25, 1397/11/05

Registrant information

Name

Reza Safaie

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3781 4191

Email address

safaei-r@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-01, 1397/05/10

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Aripiprazole augmentation of Sertraline in adolescents with obsessive-compulsive disorder

Public title
The effect of Aripiprazole augmentation of Sertraline in adolescents with obsessive-compulsive disorder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Obsessive-compulsive disorder adolescent patients
Exclusion criteria:
Pregnancy and breastfeeding Psychotic Psychiatric Disorders Mental retardation Substance abuse and alcohol abuse six months before the study began There is a physical condition that prevents the receiving of medications
Age
From **12 years** old to **19 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization using random numbers created by the computer will be performed
Blinding (investigator's opinion)
Double blinded
Blinding description
Double-blind (both patients and researchers) have been kept blind
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Kashan University of Medical Sciences
Street address
Ghotb Ravand Blvd, Kashan University of Medical Sciences, Kashan
City
kashan
Province
Isfehan
Postal code
8715988141
Approval date
2018-11-26, 1397/09/05
Ethics committee reference number
IR.KAUMS.MEDNT.REC.1397.051

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
The intensity of obsession - compulsion
Timepoint
At the time of arrival, the fourth, eighth and twelfth weeks
Method of measurement
Y-BOCS questionnaire

Secondary outcomes

1

Description
The onset of side effects of drugs
Timepoint
Weeks zero, fourth, eighth and twelfth
Method of measurement
Clinical Examination and Interview

Intervention groups

1

Description
Intervention group: Administration of 50 to 150 mg sertraline daily for 12 weeks
Category
Treatment - Drugs

2

Description
Intervention group: Administration of 50 to 150 mg of Sertraline daily and 5 to 10 mg of Aripiprazole per day for 12 weeks
Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Clinics affiliated to Kashan University of Medical Sciences

Full name of responsible person
Assaaryan Fatemeh

Street address
Kargar Nejad Hospital, Qutb Ravandi Blvd

City
kashan

Province
Isfehan

Postal code
8715973446

Phone
+98 31 5554 9111

Email
kargarnejad@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Hamidi Gholamali

Street address
Blvd. Ravandi, Kashan University of Medical Sciences

City
Kashan

Province
Isfehan

Postal code
8715973446

Phone
+98 31 5554 9111

Email
kargarnejad@kaums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
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
Reza Safaei

Position
rezident

Latest degree
Medical doctor

Other areas of specialty/work
Psychiatrics

Street address
Blvd. Ravandi, Kargar Nejad Hospital

City
Kashan

Province
Isfehan

Postal code
8715973446

Phone
+98 31 5554 9111

Email
safaei-r@kaums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Safaei reza

Position
REZIDENT

Latest degree
Medical doctor

Other areas of specialty/work
Psychiatrics

Street address
Blvd. Ravandi, Kargar Nejad Hospital

City
Kashan

Province
Isfehan

Postal code
8715973446

Phone
+98 31 5554 9111

Email
safaei-r@kaums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person

Assaryan Fatemeh
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Psychiatrics
Street address
Blvd. Ravandi, Kargar Nejad Hospital
City
Kashan
Province
Isfehan
Postal code
8715973446
Phone
+98 31 5554 9111
Email
dr.reza.safaie62@gmail.com

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