

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 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

Isfahan

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

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

Isfahan

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

Isfahan

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

Isfahan

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

Isfahan

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

Isfahan

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