

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The comparison of Aripiprazole and Quetiapine augmentation between Selective Serotonin reuptake inhibitors in refractory obsessive-compulsive disorder.

Protocol summary

Summary

The aim of the study is to investigate the comparative efficacy and tolerability of Aripiprazole versus Quetiapine over a period of 12 weeks. Inclusion criteria: Age between 18-65 years: Patients with a diagnosis of OCD. The exclusion criteria: Patients with current or previous diagnosis of psychosis. 30 patients, who are selected from psychiatry clinic in Ibn-e-Sina hospital. Patients are divided to 2 groups of A and B. In group A, aripiprazole will be given to patients as an augmentation therapy with initial dose of 5 mg/day. Then according to the patient's symptoms and tolerance, the dose will be increased up to 20 mg/day over a course of 12 weeks. In group B, patients will be treated with quetiapine with an initial dose of 50 mg/day and gradually, the dosage will be increased up to 300 mg/day. During the trial SSRI drug will be continued with maximum dose. All patients will be assessed by psychiatrist at the beginning of medication and at 4th, 8th and 12th week of treatment and at the beginning of the study and at the end of week 4, 8 and 12 Yale-Brown Obsessive-Compulsive scales (Y-BOCS), Clinical Global Impression-Severity scale (CGI-S) tests and at the beginning of the study and at the end of week 12 Hamilton Rating Scale for Depression (HDRS) test will be done. The results of the medical tests will be reviewed based on score drop testes of Y-BOCS and CGI-S.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013040612905N1**
Registration date: **2014-01-11, 1392/10/21**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-01-11, 1392/10/21

Registrant information

Name

zahra Aghili

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1842 4808

Email address

aghiliz891@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2013-05-22, 1392/03/01

Expected recruitment end date

2014-01-21, 1392/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of Aripiprazole and Quetiapine augmentation between Selective Serotonin reuptake inhibitors in refractory obsessive-compulsive disorder.

Public title

The comparison of Aripiprazole and Quetiapine augmentation between Selective Serotonin reuptake

inhibitors in refractory obsessive-compulsive disorder.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 18-65 years: Patients with a diagnosis of OCD: Patients who are non-responsive to primary treatment confirmed by a Yale-Brown Obsessive Compulsive Scale (Y-BOCS) score more than 16. The exclusion criteria: Patients with current or previous diagnosis of psychosis: Mental retardation: Substance abuse: Psychiatric disorders due to organic diseases.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Ghoreishi building, Daneshgah Street.

City

Mashhad

Postal code

Approval date

2012-10-20, 1391/07/29

Ethics committee reference number

910023

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

obsession severity

Timepoint

before intervention\ week4\week8\ week12

Method of measurement

score of Y-BOCS test

2

Description

general improvement

Timepoint

before intervention\ week 4\ week 8\ week12

Method of measurement

score of CGI test

3

Description

depression

Timepoint

before intervention\ week 12

Method of measurement

Hamilton Depression Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description

Adding Aripiprazole 5 to 20 mg per day/ Qd. in period of 12 week depend on a tolerance of the patient with the brand name: Abilazole.

Category

Treatment - Drugs

2

Description

Adding quetiapine 100 to 200 mg per day/ Qd. in period of 12 week depend on a tolerance of the patient with the brand name: Tranquiline al Sciences obsession degree.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Outpatient clinic of Ibnesina's hospital

Full name of responsible person

Dr zahra Aghili. Resident of psychiatry

Street address

Ibn-e-sina Hospital.Horeameli Ave. Boali Sq.

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person

Ardakanian Marjan

Street address

Ghoreish building, Daneshgah St.

City

Mashad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr zahra Aghili

Position

resident

Other areas of specialty/work

Street address

Ibn-e-sina hospital, Hore ameli blv.

City

Mashhad

Postal code

Phone

+98 51 1711 2721

Fax

Email

zahra.Aghili@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Ali Talaei

Position

Associate Professor

Other areas of specialty/work

Street address

Ibn-E- Sina Hospital

City

Mashhad

Postal code

Phone

+98 51 1711 2540

Fax

Email

TalaeiA@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr zahra Aghili

Position

MD

Other areas of specialty/work

Street address

Ibn-e-sina Hospital, Hore ameli blv.

City

Mashhad

Postal code

Phone

00

Fax

Email

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code
empty

Data Dictionary
empty