

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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: Abilizole.

**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: Tranqupine 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.

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**Phone**

+98 51 1711 2721

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zahra.Aghili@gmail.com

**Web page address**

#### Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

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**Full name of responsible person**

Dr Ali Talaei

**Position**

Associate Professor

**Other areas of specialty/work**

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#### 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.

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**Phone**

00

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**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*