

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of Efficacy of Aripiprazole versus Risperidone Augmentation of Selective Serotonin Reuptake Inhibitors for Treatment of Resistant Obsessive Compulsive Disorder: A Randomized Controlled Trial

Protocol summary

Study aim

To compare the efficacy of Aripiprazole versus Risperidone augmentation of SSRIs for in the treatment of resistant OCD.

Design

Two arm parallel group randomised trial, single blinded

Settings and conduct

Lahore general hospital

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients of age 16-65 years of either gender Patients diagnosed with obsessive compulsive disorder (as per operational definition) with Y-BOCS score ≥ 16 . Exclusion Criteria: Pregnant females. Patient allergic to trial drugs. Patient having an organic cause for their symptoms. Patient with comorbid conditions that aggravate the condition or develop depression and anxiety.

Intervention groups

In group A, patients will be given Aripiprazole started with a 2.5 mg daily dose and will be gradually increased to 10 mg daily by the end of the second week. In group B, Risperidone initiated with a 1 mg daily dose and was gradually increased to 2 mg daily by the end of the second week.

Main outcome variables

Y-BOCS SCORE

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230526058298N1**

Registration date: **2023-06-23, 1402/04/02**

Registration timing: **prospective**

Last update: **2023-06-23, 1402/04/02**

Update count: **0**

Registration date

2023-06-23, 1402/04/02

Registrant information

Name

Muhammad Irfan Jamil

Name of organization / entity

Postgraduate Medical institute Lahore, Ameer-ud-din medical college

Country

Pakistan

Phone

+92 311 3773799

Email address

irfanravian51@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-01, 1402/04/10

Expected recruitment end date

2024-01-31, 1402/11/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Efficacy of Aripiprazole versus Risperidone Augmentation of Selective Serotonin Reuptake Inhibitors for Treatment of Resistant Obsessive Compulsive Disorder: A Randomized Controlled Trial

Public title

Comparison of Efficacy of Aripiprazole versus Risperidone

Augmentation of Selective Serotonin Reuptake Inhibitors for Treatment of Resistant Obsessive Compulsive Disorder: A Randomized Controlled Trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

□ Patients of age 16-65 years of either gender □ Patients diagnosed with obsessive compulsive disorder (as per operational definition) with Y-BOCS score ≥ 16 .

Exclusion criteria:

□ Pregnant females □ Patient allergic to trial drugs □ Patient having an organic cause for their symptoms □ Patient with comorbid conditions that aggravate the condition or develop depression and anxiety

Age

From **16 years** old to **65 years** old

Gender

Both

Phase

1

Groups that have been masked

- Participant

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization process will be performed by an principal researcher who is directly involved in the study. The randomization sequence will be generated using a random number generator, and participants will be assigned to their respective groups based on the order of enrollment. The allocation sequence will be concealed from the patients, ensuring that they remain blinded to the upcoming assignments.

Blinding (investigator's opinion)

Single blinded

Blinding description

The allocation sequence will be concealed from the patients, ensuring that they remain blinded to the upcoming assignments. the participants involved in the study will not be aware of their group assignment or the specific treatment they are receiving. However, the investigators and research staff will be aware of the group assignments.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

AMC/PGMI/LAHORE GENERAL HOSPITAL

Street address

Ferozpur road lahore

City

LAHORE

Postal code

54000

Approval date

2021-09-21, 1400/06/30

Ethics committee reference number

00/64/21

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

YALE-BROWN OBSESSIVE COMPULSIVE SCALE

Timepoint

3 months

Method of measurement

scoring system

Secondary outcomes

empty

Intervention groups

1

Description

In group A: Aripiprazole started with a 2.5 mg daily dose and will be gradually increased to 10 mg daily by the end of the second week. Treatment will be continued for 12 weeks.

Category

Treatment - Drugs

2

Description

In group B, Risperidone initiated with a 1 mg daily dose and was gradually increased to 2 mg daily by the end of the second week. Treatment will be continued for 12 weeks.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Lahore general hospital lahore

Full name of responsible person

Huma Kanwal

Street address

ferozpur road lahore

City

lahore

Postal code

54000

Phone

+92 333 3222453

Email

drhumazaheer13@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Postgraduate Medical Institute Lahore

Full name of responsible person

Irfan Jamil

Street address

Ferozpur Road Lahore

City

Lahore

Postal code

54000

Phone

+92 311 3773799

Email

irfanravian51@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Postgraduate Medical Institute Lahore

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

Post graduate Medical Institute Lahore

Full name of responsible person

Irfan Jamil

Position

Consultant

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Ferozpur Road Lahore

City

Lahore

Province

Punjab

Postal code

54000

Phone

+92 311 3773799

Email

irfanravian51@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Postgraduate Medical Institute Lahore

Full name of responsible person

Irfan Jamil

Position

Consultant

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Ferozpur road Lahore

City

Lahore

Province

Punjab

Postal code

54000

Phone

+92 311 3773799

Email

irfanravian51@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

lahore general hospital lahore

Full name of responsible person

Huma Kanwal

Position

postgraduate resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

khanpur

City

khanpur

Province

punjab

Postal code

64100

Phone

+92 68 5571035

Email

drhumazaer13@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

primary outcome only

When the data will become available and for how long

results for lifelong

To whom data/document is available

to all

Under which criteria data/document could be used

for reference

From where data/document is obtainable

email

What processes are involved for a request to access data/document

email

Comments