Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 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
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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

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Lahore general hospital lahore

Full name of responsible person
Huma Kanwal

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ferozpur road lahore

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Postgraduate Medical Institute Lahore

Full name of responsible person
Irfan Jamil

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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

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Person responsible for updating data

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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