Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

A survey about comparison of augmentation therapy in refractory obsessive-compulsive disorder patients; Aripiprazole vs. Risperidone

Protocol summary

Summary

This RCT aimed to compare augmentation effects of Aripiprazole versus Risperidone in treatment of refractory obsessive-compulsive disorder (OCD). In this double-blinded RCT, 100 patients which according on DSV-IV-TR has been recognized as the refractory OCD selected with non-random method. They were captured from psychiatry clinics of Kashan University of Medical Sciences. After acquiring consent from patients they were randomized into two identical groups. In addition to taking SSRI drugs for every group, we added daily dose of 5 mg Aripiperazole to one group and 1.5 mg to another group for 12 weeks. The most important inclusion criteria were; Age between 18-60 years; the Yale-Brown obsessive-compulsive scale (Y-BOCS) ≥16 and suffering from OCD whilst were taken a therapeutic dose of SSRI drugs at least for 12 weeks. The most important exclusion criteria were; breast feeding and pregnancy, any acute or severe physical diseases occurring during the study, more than four weeks loss to follow-up. The efficacy of treatment as the primary outcome was measured by Yale-Brown Obsessive Compulsive Scale score and was compared before trial and in 4th, 8th and 12th weeks and any severe side effects of traetment were measured as the secondary outcome.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015110424882N1**
Registration date: **2016-08-04, 1395/05/14**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-08-04, 1395/05/14

Registrant information

Name
Mahboobeh Borna
Name of organization / entity
Kashan University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 31 5547 1370
Email address
mahboobehborna@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2013-04-21, 1392/02/01

Expected recruitment end date

2014-04-21, 1393/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A survey about comparison of augmentation therapy in refractory obsessive-compulsive disorder patients; Aripiprazole vs. Risperidone

Public title

Augmentation therapy comparison in refractory obsessive-compulsive disorder with Aripiprazole vs. Risperidone

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 18-60 years;the Yale-Brown obsessive-compulsive scale (Y-BOCS) ≥16 and suffering from OCD whilst were taken a therapeutic dose of SSRI drugs at least for 12 weeks;negative history of: pregnant or breastfeeding in women; psychotic, bipolar mood, and severe depressive disorders in DSM-IV-TR axis I; any known disorder in DSM-IV-TR axis II like personality disorders or mental retardation; drug and alcohol abuse in the last six months before study; any physical disease impeding the use of Risperidone or Aripiprazole; not psychotherapy during the study. Exclusion criteria: Any acute or severe physical diseases occurring during the study; more than four weeks loss to follow-up; severe side effects during the study; not using contraceptive methods in females.

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
ثبت نشده

Secondary trial Id
-

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Kashan University of Medical Sciences ethic commetee in health sciences

Street address
Ghotbe ravandi, Blv, Vice Chancellor of Research & Technology

City
Kashan

Postal code
8715988141

Approval date
2013-08-22, 1392/05/31

Ethics committee reference number
9270

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
Severity of symptoms of OCD

Timepoint
Basline and every 4 weeks

Method of measurement
Y_BOCS

Secondary outcomes

1

Description
Unwanted side effects of drugs

Timepoint
Every 4 weeks

Method of measurement
Interview

Intervention groups

1

Description
In a group of patients in addition to SSRI drugs, Aripiprazole, production of sobhan corporation, begun with 2.5 mg and increased gradually to 10 mg, at the end of second week. All of patients were visited 8 times by psychiatrist. In cases of side effects incidence it was treated by lowering doses of drug and beginning more gradually, again or was taken necessary drugs (Propranolol, Lorazepam and Piperidine) to control side effects

Category
Treatment - Drugs

2

Description
In other group also, in addition to SSRI drugs,

Risperidone, production of sobhan corporation, begun with 1 mg and increased gradually to 2 mg, at the end of the first week. All of patients were visited 8 times by psychiatrist. In cases of side effects incidence it was treated by lowering doses of drug and beginning more gradually, again or was taken necessary drugs (Propranolol, Lorazepam and Piperidine) to control side effects

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinical psychiatrist of Kashan University of Medical Sciences

Full name of responsible person

Fatemeh Assarian

Street address

Ghotbe ravanvi Blv. Kargarnegad hospital

City

Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences, Dr Gholamali Hamidi

Full name of responsible person

Dr Fatemeh Assarian

Street address

Ghotbe ravandi Blv. Kargarnejad hospital

City

Kashan

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, Dr Gholamali Hamidi

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

Kashan University of Medical Sciences

Full name of responsible person

Dr Fatemeh Assarian

Position

Assistant professor

Other areas of specialty/work

Street address

Ghotbe ravandi Blv. Kargarnejad hospital

City

Kashan

Postal code

8715973446

Phone

+98 31 5554 9111

Fax

Email

fa_assar@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr Fatemeh Assarian

Position

Assistan professor

Other areas of specialty/work

Street address

Ghotbe ravandi Blv. Kargarnead hospital

City

Kashan

Postal code

8715973446

Phone

+98 31 5554 9111

Fax

Email

fa_assar@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr Mahboobeh Borna

Position

resident

Other areas of specialty/work

Street address

Ghotbe ravandi Blv. Kargarnejad hospital

City

Kashan

Postal code

8715973446

Phone

+98 31 5547 1370

Fax

Email

mahboobehborna@yahoo.com

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