

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effectiveness of adding Buspirone to SSRI in the control of signs and symptoms of Obsessive-Compulsive Disorder

Protocol summary

Study aim

Buspirone augmentation to SSRI in treatment of OCD

Design

This is a randomized clinical trial with a parallel group design of 60 patients, enrolled between January 2019 and September 2020

Settings and conduct

outpatients suffer OCD come to 22 Bahman and Bu ALI Hospitals in Qazvin City.

Participants/Inclusion and exclusion criteria

OCD patients according to Yale Brown criteria

Intervention groups

Intervention group receives Buspirone Plus Sertraline.
Control group takes Sertraline plus Placebo

Main outcome variables

Yale Brown Scale under 21

+98 28 3357 8505

Email address

fzahedian@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2020-01-21, 1398/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of adding Buspirone to SSRI in the control of signs and symptoms of Obsessive-Compulsive Disorder

Public title

The effect of adding buspirone to SSRIs in the treatment of obsessive-compulsive disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Yale Brown criteria scale for Obsessive Compulsive Disorder (OCD) > 21 score Patients will be selected according to the demographic information as: age/gender/marital status/education/job/onset age of illness/previous treatment/ age should be 18-60 The other psychiatric disease should not be existed opioid/stimulant/should not be existed Liver and Kidney diseases should not be existed

Exclusion criteria:

Yale Brown Scale below 21 scale Opioid use disorders Stimulant use disorders Liver Failure Kidney Failure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180303038927N1**

Registration date: **2019-01-01, 1397/10/11**

Registration timing: **prospective**

Last update: **2019-01-01, 1397/10/11**

Update count: **0**

Registration date

2019-01-01, 1397/10/11

Registrant information

Name

Mojtaba Shirkhani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Restricted randomization with Random Allocation Rule

Blinding (investigator's opinion)

Single blinded

Blinding description

this study is a Single Blind Study, that Interventional and Control group are not aware of their group. but the responsible person is aware and know them.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

National ethics committee in medical research

Street address

Rah Ahan Station 22 Bahman Hospital

City

Qazvin

Province

Qazvin

Postal code

3416899198

Approval date

2000-12-03, 1379/09/13

Ethics committee reference number

ir.qums.rec.1397.218

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 scale according to Yale Brown Questionnaire

Timepoint

Comparison of Yale Brown scale in Buspirone group 6 weeks after the treatment.

Method of measurement

Yale Brown Scale

2

Description

Obsession scale according to Yale Brown Questionnaire

Timepoint

Comparison of Yale Brown scale in Buspirone group in the end of the treatment.

Method of measurement

Yale Brown Scale

3

Description

Obsession scale according to Yale Brown Questionnaire

Timepoint

Comparison of Yale Brown scale in Buspirone group with Placebo Group six weeks after the treatment.

Method of measurement

Yale Brown Scale

4

Description

Obsession scale according to Yale Brown Questionnaire

Timepoint

Comparison of Yale Brown scale in Buspirone group with Placebo Group in the end of the treatment.

Method of measurement

Yale Brown Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 30 patients to receive Sertraline plus Buspirone for 3 months 50 to 200 mg Sertraline plus until 30 mg Buspirone.

Category

Treatment - Drugs

2

Description

In 30 Placebo group that only receive sertraline 50-200 mg plus placebo that is exactly like the tablet of Buspirone and contains cellulose or starch.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

22 Bahman Hospital

Full name of responsible person

Faezeh Zahedian

Street address

Railway Station Parastar Street. 22 Bahman Hospital

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2**Recruitment center****Name of recruitment center**

Bu Ali Hospital

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Grant name

By research deputy of Qazvin University of Medical SCIENCES

Grant code / Reference number**Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Qazvin University of Medical Sciences

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**

Qazvin University of Medical Sciences

Full name of responsible person

Mojtaba Shirkhani

Position

Psychiatry Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Academic Instructor

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Person responsible for updating data

Contact

Name of organization / entity
Qazvin University of Medical Sciences
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Specialist
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The Augmentation effect of Buspirone to Sertraline IN
OCD treatment

When the data will become available and for how long

about one year

To whom data/document is available

for academic persons and patients

Under which criteria data/document could be used

for persons wants to know about OCD

From where data/document is obtainable

articles

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

by searching on the Internet

Comments

OCD patients suffer from their illness,they have no complete cure with one drug,augmentation may be more efficient