Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 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 Sebtember 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

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
+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

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 responsibe 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 recieve 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 recieve 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
City
Qazvin
Province
Qazvin
Postal code
3416899198
Phone
+98 28 3357 8505
Email
f.zahedian@qums.ac.ir

2

Recruitment center
Name of recruitment center
Bu Ali Hospital
Full name of responsible person
Faezeh Zahedian
Street address
Naderi Street
City
Qazvin
Province
Qazvin
Postal code
3416899695
Phone
+98 28 3333 2930
Email
f.zahedian@qums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Faezeh Zahedian
Street address
Railway Station Parastar Ave.22 Bahman Hospital
City
Qazvin
Province
Qazvin
Postal code
3416899198
Phone
+98 28 3357 8505
Email
f.zahedian@qums.ac.ir
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
Street address
Parastar street Rail way station
City
Qazvin
Province
Qazvin
Postal code
3416899198
Phone
+98 28 3357 8505
Email
m.shirkhani@Qums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Faezeh Zahedian
Position
Academic Instructor
Latest degree

Specialist

Other areas of specialty/work
Psychiatrics

Street address
Rail Way Station-Parastar Street

City
Qazvin

Province
Qazvin

Postal code
3416899198

Phone
+98 28 3355 5978

Email
F.Zahediani@QUMS.AC.IR

Person responsible for updating data

Contact

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Faezeh Zahedian

Position
academic instructor

Latest degree
Specialist

Other areas of specialty/work
Psychiatrics

Street address
Parastar Street 22 Bahman Hospital

City
Qazvin

Province
Qazvin

Postal code
3416899198

Phone
+98 28 3357 8505

Email
f.zahedian@qums.ac.ir

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