Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Sep 2026

Evaluation of Bumetanide’s Effect on Symptom Characteristics (Based on YBOCS) in Patients with Resistant Obsessive Compulsive Disorder Comparing to Selective Serotonin Reuptake Inhibitors

Protocol summary

Study aim
Evaluation of bumetanide effect on symptom characteristics in patients with obsessive compulsive disorder based on yale brown obsessive compulsive disorder scale

Design
Single-Blinded, Randomized Controlled Clinical Trial, Selected Sample Size: 31 Subject for each arm

Settings and conduct
Roozbeh Hospital- Imam Khomeini hospital Complex- National Brain Mapping Lab The patients will be selected based on the psychiatrist diagnosis and then reassessed by the trained clinical psychologist, the primary tests including wechsler and depression/ anxiety will be done. For all the subjects, baseline assessment of disorder severity and dimensions, blood taking for gene expression and neurocognitive and neuroimaging will be done. all of these items will be reoperate after trial completion.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: 1. Confirmed diagnosis of Obsessive Compulsive Disorder which is resistant to the Selective Serotonin Reuptake Inhibitors (SSRIs) 2. Age range between 18 and 50 years Exclusion Criteria: 1. Psychiatric Comorbidity like: Schizophrenia and bipolar disorder 2. Any History of Neurological Disorders 3. Pregnancy and Breast Feeding 4. Concurrent use of opioids, Stimulants and alcohol 5. Any History of Cardiovascular Disorders 6. Any History of Liver Related Disorders 7. Any History of Renal Disorders 7. Sulfur Sensitivity 8. Benzodiazepine use within at least previous 3 months

Intervention groups
1. Resistant Patient Group that Receive Bumetanide in addition to the background Serotonin Reuptake Inhibitors (SRIs). 2. Resistant Patient Group that Receive the standard treatment (Antipsychotics) in addition to the background Serotonin Reuptake Inhibitors (SRIs)

Main outcome variables
1. Course of Alteration in Symptom Severity in Response to the Added Medication 2. Course of Adverse Drug Reaction in Association with the Added Medication

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140120016280N3**
Registration date: **2019-08-11, 1398/05/20**
Registration timing: **prospective**

Last update: **2019-08-11, 1398/05/20**
Update count: **0**

Registration date
2019-08-11, 1398/05/20

Registrant information

Name
Mahmoudreza Hadjighassem
Name of organization / entity
TUMS
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-08-23, 1398/06/01

Expected recruitment end date

2020-06-19, 1399/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Bumetanide’s Effect on Symptom Characteristics (Based on YBOCS) in Patients with Resistant Obsessive Compulsive Disorder Comparing to Selective Serotonin Reuptake Inhibitors

Public title

Evaluation of Bumetanide’s Effect on Symptom Characteristics in Patients with Obsessive Compulsive Disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1. Confirmed Diagnosis of Resistant OCD Age range of 18-50 years IQ level more than 80 based on Wechsler Adult Intelligence Scale

Exclusion criteria:

Comorbidities like MDD, Bipolar Disorder, Personality Disorder, Schizophrenia Drug Adverse Effects Pregnancy, Breast Feeding (Based on self report data and urinary detection) Drug and alcohol use and dependance (Based on self report data and urinary detection) Benzodiazepine use within 3 preceding months Furesemide and other diuretic and cardiovascular drugs use Sulfur and its derivatives sensitivity Neurological Disorders(seizure, trauma, ischemic stroke, surgery) Presence of MRI SCanning absolute and partial contraindications

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Investigator

Sample size

Target sample size: **31**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization process will be done using permuted block randomization with blocks in size 4. Regarding determined sample size 70, Quadratic blocks will be produced using the online website: www.sealedenvelope.com.

Blinding (investigator's opinion)

Single blinded

Blinding description

Since the current study will be performed within the neuropsychiatry context and the probability of bias formation and placebo effects are considerable, the main investigator that is assessor and also the author of the manuscript would be held blinded. such a way that, the primary neuropsychological assessments will be executed by the trained clinical psychologist.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Tehran University of Medical Sciencesl Sciences

Street address

13th floor, Block A, Ministry of Health and Medical Education, Simaye Iran Street, Qods Town, Tehran, Iran

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Province

Tehran

Postal code

1467664961

Approval date

2018-11-27, 1397/09/06

Ethics committee reference number

IR.TUMS.VCR.REC.1397.628

Health conditions studied

1

Description of health condition studied

Obsessive Compulsive Disorder (OCD)

ICD-10 code

F42

ICD-10 code description

Obsessive-compulsive disorder

Primary outcomes

1

Description

Symptom (Obsession and Compulsions) Severity Based on Yale Brown Obsessive Compulsive Disorder Scale

Timepoint

Assessment of Severity and pattern of symptoms : 1. In the beginning of Study and before intervention, 2. 10 days after intervention, 3. 20 days after intervention, 4. 30 days after intervention, 5. 40 days after intervention, 6. 50 days after intervention, 7. 60 days after intervention, 8. 70 days after intervention

Method of measurement
Validated Yale Brown Obsessive Compulsive Disorder Scale

Secondary outcomes

1

Description
Alteration in Neuro-Cognitive Functioning
Timepoint
In the Beginning of Study and then after Study Completion
Method of measurement
the Cambridge Neuropsychological Test Automated Battery (CANTAB)

2

Description
Assessment of Functional Reorganization of Large Scale Brain Networks
Timepoint
Before the beginning of the clinical trial and immediately after the end of that
Method of measurement
Functional Magnetic Resonance Imaging

3

Description
Expression of Na-K-Cl Co transporter (NKCC1) in Lymphocytes of the Peripheral Blood
Timepoint
Before the Beginning of the Clinical Trial and Immediately after that
Method of measurement
Real Time Polymerase Chain Reaction (RT-PCR) and Western Analysis

4

Description
Expression of K-Cl Co transporter in lymphocyte of the peripheral blood
Timepoint
Before the beginning of the Clinical Trial and Immediately after that
Method of measurement
Real Time Polymerase Chain Reaction (RT-PCR) and Western Analysis

Intervention groups

1

Description
Resistant Patient Group that receive Bumetanide in addition to the background Serotonin Reuptake Inhibitors (SRIs). Bumetanide, 3-butylamino-4-phenoxy-5-sulfamoylbenzoic acid, which is a chemical compound that inhibits Na-K-Cl-Co transporter, will be added to the background medications in two phases including: titration, steady state and then will be tapered down. This Therapeutic protocol will be started by 1 milligram daily oral dose and then will be increased to 2 milligrams daily based on patient response and adverse effects profile
Category
Treatment - Drugs

2

Description
Resistant Patient Group that Receive the standard treatment (Antipsychotics) in addition to the background Serotonin Reuptake Inhibitors (SRIs). Generally, the next standard treatment line in these patients is using low-dose second generation antipsychotics. The most common prescribed ones are risperidon and olanzapine.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Roozbeh Hospital
Full name of responsible person
Mahmoudreza Hadjighassem, Mohammad Arbabi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Sahraian
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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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Mahmoudreza Hadjighassem

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Neuroscience

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Person responsible for scientific inquiries

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Person responsible for updating data

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Name of organization / entity
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Lida Shafaghi

Position
PhD Student

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

Data Dictionary
Not applicable

Title and more details about the data/document
Information of the main (primary outcome) and the secondary outcomes like gene expression changes and neuronal networks reorganization outcome can be shared.

When the data will become available and for how long
6 months after publication of results

To whom data/document is available
Research data will be available for the researchers of universities and scientific institutes and also relevant investigators of the industries.

Under which criteria data/document could be used
The data will be available, when the samples are taken out, all the stages of the project are completed and finalized, and the results are published.

From where data/document is obtainable
1. Dr Mahmoudreza Hdjighassem First Address: Neuroscience Group, Reihaneh Department, Keshavarz BLVD, Imam Khomeini Hospital Complex. Tehran. Second Address: 87, School of Advanced Technologies in Medicine, Italia st, Keshavarz blv. Tehran. Cell Phone Number: 09126779102 Faculty Phone Number: 02143052000 Fax Number: 02188991117 Email Address: mhadjighassem@tums.ac.ir 2. Lida Shafaghi Address: 87, School of Advanced Technologies in Medicine, Italia st, Keshavarz blv. Tehran. Cell Phone Number: 09123832340 Fcaulty Number: 0214305200 Email Address: Lidashafaghi@gmail.com

What processes are involved for a request to access data/document
In order to receive the information, firstly the applicants send the formal application to the correspondent of the present proposal, Dr. Hadjighassem (Dean of the Department of Neuroscience and Addiction studies, School of Advanced Technologies in Medicine) and then they will be informed of the details of the data reception (including timing-that will be tried to be within the shortest possible interval- and the way of the addressing the available data like email or in person.

Comments