

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 218899111823

##### Email address

mhadjighassem@tums.ac.ir

##### 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](http://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  
**City**  
Tehran  
**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 risperidone 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

##### Street address

South Kargar Street, Tehran , Iran

##### City

Tehran

##### Province

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##### Postal code

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##### Email

hosp\_roozbeh@tums.ac.ir

##### Web page address

<http://roozbehhospital.tums.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Mohammad Ali Sahraian

##### Street address

Sixth Floor, Central Organization of Tehran University of Medical Science, Qods Street

##### City

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##### Province

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**Email**  
tums\_edu@tums.ac.ir  
**Web page address**  
<http://vcr.tums.ac.ir/>  
**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  
**Street address**  
87, Third floor, Building No.2, School of Advanced Technologies in Medicine, Italia st, Keshavarz blv.  
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## Person responsible for scientific inquiries

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Tehran University of Medical Sciences  
**Full name of responsible person**  
Mahmoudreza Hadjighassem  
**Position**  
Associate Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
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## Person responsible for updating data

**Contact**  
**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Lida Shafaghi  
**Position**  
PhD Student  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Neuroscience  
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87, Third floor, Building No.2, School of Advanced Technologies in Medicine, Italia st, Keshavarz blv.  
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lshafaghi@razi.tums.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

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 Faculty 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