

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Study of Buprenorphine augmentation in regular treatment of resistant obsessive compulsive disorder

#### Protocol summary

##### Summary

Objectives: To assess the effect of Buprenorphine augmentation in regular treatment of resistant obsessive-compulsive disorder. Design: a before and after clinical trial. Setting and conduct: Eligible patients who are Patients with primary Obsessive Compulsive Disorder who received regular treatment of resistant obsessive-compulsive disorder but failed to respond to treatment and will refer to psychological clinics of Farshchian hospital during the study period will be enrolled in to the trial. Inclusion criteria: (a) Patients with primary Obsessive Compulsive Disorder who received minimum of 2 different Selective Serotonin Reuptake Inhibitor for a period of 16 weeks in two separate rotations but failed to respond to treatment (less than 25% in symptom regression); (b) age between 18 to 60 years old; (c) scores of more than 16 according to Yale-Brown Obsessive Compulsive Scale (Y-COBS) Exclusion criteria: (a) receiving any other opioid medications; (b) having any history of alcohol or substance abuse; (c) received any electroconvulsive therapy during the last two months; (d) having any serious diseases which require long term medical treatment such as diabetes, high blood pressure, rheumatoid arthritis, cardiovascular diseases, respiratory diseases, thyroid diseases or gastrointestinal diseases; (e) any signs of psychotic disorders, such as bi-polar schizophrenia or similar; (f) being at a great risk of suicide attempt; (g) any pregnant woman or any woman who intend pregnancy during the next 3 months; (h) any serious- non psychological diseases; (i) any upcoming surgery which needs anesthesia or deep Sedation; (j) patient is a candidate to receive electroconvulsive therapy. Intervention: Tablet Buprenorphine 250 mg would be prescribed daily for 8 weeks and increased 500mg weekly with respect to patient tolerance. We will assess the Yale-Brown Obsessive Compulsive Scale before and after Buprenorphine augmentation in regular treatment using questionnaire.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015062422901N1**  
Registration date: **2015-12-06, 1394/09/15**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-12-06, 1394/09/15

##### Registrant information

##### Name

Amin Reihani

##### Name of organization / entity

Hamadan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 3827 1066

##### Email address

a.reihani@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor of research of Hamadan university of medical sciences

##### Expected recruitment start date

2015-09-23, 1394/07/01

##### Expected recruitment end date

2016-09-22, 1395/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

Study of Buprenorphine augmentation in regular treatment of resistant obsessive compulsive disorder

**Public title**

Study of Buprenorphine augmentation in regular treatment of resistant obsessive compulsive disorder

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: (a) patients with primary Obsessive Compulsive Disorder who received minimum of 2 different Selective Serotonin Reuptake Inhibitor for a period of 16 weeks in two separate rotations but failed to respond to treatment (less than 25% in symptom regression); (b) age between 18 to 60 years old; (c) scores of more than 16 according to Yale-Brown Obsessive Compulsive Scale (Y-COBS) Exclusion criteria: (a) receiving any other opioid medications; (b) having any history of alcohol or substance abuse; (c) received any electroconvulsive therapy during the last two months; (d) having any serious diseases which require long term medical treatment such as diabetes, high blood pressure, rheumatoid arthritis, cardiovascular diseases, respiratory diseases, thyroid diseases or gastrointestinal diseases; (e) any signs of psychotic disorders, such as bi-polar schizophrenia or similar; (f) being at a great risk of suicide attempt; (g) any pregnant woman or any woman who intend pregnancy during the next 3 months; (h) any serious- non psychological diseases; (i) any upcoming surgery which needs anesthesia or deep Sedation; (j) patient is a candidate to receive electroconvulsive therapy.

**Age**

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

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **23**

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Hamadan University of Medical Sciences

**Street address**

Farshchian Hospital

**City**

Hamadan

**Postal code****Approval date**

2015-06-20, 1394/03/30

**Ethics committee reference number**

IR.UMSHA.REC.1394.151

**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**

Obsessive Compulsive Disorder severity

**Timepoint**

before intervention and end of 1,2,3,4,5 weeks after that

**Method of measurement**

Yale Brown Scale

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Tablet Buprenorphine 250 mg would be prescribed daily for 8 weeks and increased 500mg weekly with respect to patient tolerance

**Category**

Treatment - Drugs

**2****Description**

The regular treatment is to start with an SSRI (Selective Serotonin Reuptake Inhibitors) or clomipramine for 4 to 6 weeks . If treatment with clomipramine or an SSRI is unsuccessful, many therapists augment the first drug by the addition of valproate, lithium, carbamazepine, or an atypical antipsychotic such as risperidone.

**Category**

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Farshchian Hospital

**Full name of responsible person**

Dr Ali Ghaleiha

**Street address**

Farshchian Hospital, Mirzade Eshghi Ave, Hamadan

**City**

Hamadan

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor of research of Hamadan university of medical sciences

**Full name of responsible person**

Dr Saeid Bashirian

**Street address**

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

**City**

Hamadan

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor of research of Hamadan university of medical sciences

**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**

Hamadan University of Medical Sciences

**Full name of responsible person**

Dr Amin Reihani

**Position**

Resident of Psychiatry

**Other areas of specialty/work**

**Street address**

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**Email**

dr.reihani.a@gmail.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Hamadan University Of Medical Sciences

**Full name of responsible person**

Dr Ali Ghaleiha

**Position**

Associate Professor

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Hmadan University of Medical Sciences

**Full name of responsible person**

Amin Reihani

**Position**

Resident of psychiatry

**Other areas of specialty/work**

**Street address**

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**Fax**

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**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*