

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

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

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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

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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