Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 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
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+98 81 3827 1066
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Recruitment status

Recruitment complete

Funding source

Vice chancellor of research of Hamadan university of medical scienses

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 Siences

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 az 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 scienses
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 scienses
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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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