

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Comparing the clinical response of obsessive-compulsive patients refractory to serotonin reuptake inhibitor regimen with and without lamotrigine; a double-blind placebo controlled study

#### Protocol summary

##### Summary

The 60 patients were entered in this study. Patients were diagnosed with obsessive-compulsive disorder, based on structured clinical interviews by skilled psychiatrist on the basis of the DSM IV TR criteria, and received at least two trimester trials of serotonin reuptake inhibitors while still suffering from a Yale brown obsessive-compulsive score of 21 and higher who were resistant to treatment. Before entering the study, all the patients, their parents or their lawyer sign the informed consent. The subjects are selected from private clinical psychiatric centers in Rasht and randomized by a computer based program into two groups, each containing 30 patients. Based on the group they are assigned to, the patients receive placebo or Lamotrigine. Both groups receive the same number of identical capsules during the study. Lamotrigine dosage starts at 25 mg daily, which will increase 25 mg each week to reach the target level of 100 mg. Then the dosage will be maintained at 100 mg until the end of the study. Yale Brown Obsessive-Compulsive Scale is checked on days 0, 60 and 90 by a skilled clinical PhD psychologist who performs the whole study in a double-blind method. The duration of the study is 90 days. Finally the changes in the Yale Brown Obsessive-Compulsive Scale on day 90 compared to day zero will be assessed. At last, if any of the patients need any more therapeutic care, it will be provided.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014031717045N1**  
Registration date: **2014-10-04, 1393/07/12**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-10-04, 1393/07/12

##### Registrant information

###### Name

Seyyed Mohammad Rasool Khalkhali

###### Name of organization / entity

Guilan university of medical sciences, Shafa hospital

###### Country

Iran (Islamic Republic of)

###### Phone

+98 13 1666 2325

###### Email address

khalkhali@gums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Investigator

##### Expected recruitment start date

2014-04-21, 1393/02/01

##### Expected recruitment end date

2016-04-21, 1395/02/02

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the clinical response of obsessive-compulsive patients refractory to serotonin reuptake inhibitor regimen with and without lamotrigine; a double-blind placebo controlled study

##### Public title

Comparing the clinical response of obsessive-compulsive

patients refractory to serotonin reuptake inhibitor regimen with and without lamotrigine; a double-blind placebo controlled study

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

Inclusion criteria: OCD diagnosis on axis I based on DSM IV TR; Ages between 16 and 60; Yale Brown Obsessive Compulsive Score of more than 21 Exclusion criteria: Active psychotic disorder such as schizophrenia, psychotic bipolar disorder and major depressive disorder; Major organic disorder; Organic brain disorder; Drug and substance abuse; Mental retardation; Pregnancy and lactation; During psychotherapy

#### **Age**

From **16 years** old to **60 years** old

#### **Gender**

Both

#### **Phase**

2-3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **60**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Ethic Committee in Research and Technology Branch

###### **Street address**

Shahid Beheshti BLVD

###### **City**

Rasht

###### **Postal code**

##### **Approval date**

2014-03-17, 1392/12/26

##### **Ethics committee reference number**

1920452601

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Obsessive-compulsive patients

##### **ICD-10 code**

F42

##### **ICD-10 code description**

The essential feature is recurrent obsessional thoughts or compulsive acts.

### **Primary outcomes**

#### **1**

##### **Description**

Clinical response is measured by Yale Brown Obsessive Compulsive Scale

##### **Timepoint**

The day 0, 60 and 90

##### **Method of measurement**

Yale Brown Obsessive Compulsive Scale

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

##### **Description**

Patients in intervention group continue the previous medication, Serotonin Reuptake Inhibitors, all over the study. Intervention group receive capsules containing lamotrigine, starting at 25 mg daily, titrated up to 25 mg weekly to reach the target level of 100 mg at the end of the 4th week. At this point, the dosage will be maintained at the same level until the end of the study, which lasts 90 days.

##### **Category**

Treatment - Drugs

#### **2**

##### **Description**

Patients in the placebo group continue previous medication, Serotonin Reuptake Inhibitors, all over the study. Patients in the placebo group receive one capsule daily. The number, shape and size of the capsules in the placebo group are exactly the same as those in the intervention group.

##### **Category**

Placebo

### **Recruitment centers**

#### **1**

##### **Recruitment center**

###### **Name of recruitment center**

Two private psychiatric clinic

###### **Full name of responsible person**

**Street address****City**

Rasht

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Guilan University of Medical Sciences

**Full name of responsible person**

Vice chancellor for research, Guilan University of Medical Sciences

**Street address**

West Shahid Beheshti BLVD

**City**

Rasht

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Guilan 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**

Guilan University of Medical Sciences

**Full name of responsible person**

Setareh Aram

**Position**

Psychiatric Assistant

**Other areas of specialty/work****Street address**

Shafa Hospital- 15th street

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Guilan University of Medical Sciences

**Full name of responsible person**

Seyyed Mohammad Rasool Khalkhali

**Position**

Assistant Professor of Psychiatry

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Guilan University of Medical Sciences

**Full name of responsible person**

Seyyed Mohammad Rasool Khalkhali

**Position**

Assistant Professor of psychiatry

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**Postal code****Phone**

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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*