

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

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Assistant Professor of Psychiatry

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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*