Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of Riluzol effect as adjunctive therapy in patients with standard treatment-resistant obsessive-compulsive disorder

Protocol summary

Study aim

1- Determining the mean score of Y-BOCS in 2 groups of control and drug 2- Determining the average score in 12 weeks after starting the study Comparison of Y-BOCS change in week 0 and 12 between control and drug groups 4- The amount of side effects recorded between the two control and drug groups in week 12

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 22 patients. Excel software rand function was used for randomization. Patients are randomly divided into two groups of drugs and placebo. We prepare the medicine and placebo with the same appearance (including color, size and design) and in the same package with a dose of 50 mg and provide it to the patients.

Settings and conduct

By referring the qualified patients to the office of Dr. Sayyah Bargard, a Psychiatrist, after examining the patient's condition, the drugs were randomly selected and delivered to the patient. All patients were followed up for 12 weeks.

Participants/Inclusion and exclusion criteria

1. People who are recognized as having obsessive-compulsive disorder by the DSM-V standard 2. Has no other mental disorder. 3. Has not been diagnosed with any respiratory disorders. 4. Do not consume alcohol and do not use drugs or stimulants. 5. Be between 18 and 65 years old. 6. The person in question should be treated with SSRI drug for at least 3 months with the maximum dose and has a score of 20 or higher in the Y-BOCS criterion.

Intervention groups

Both groups of patients were told to take one pill every night for 12 weeks, and to report the symptoms of taking the pill by phone or in the attending physician's office. Medication or discontinuation is done.

Main outcome variables

Finding a low-complication and effective drug as adjunctive therapy in refractory obsessive-compulsive disorder.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151103024853N5**
Registration date: **2020-11-04, 1399/08/14**
Registration timing: **retrospective**

Last update: **2020-11-04, 1399/08/14**
Update count: **0**

Registration date

2020-11-04, 1399/08/14

Registrant information

Name

Leila Kouti

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 61 3373 8379

Email address

kouti-l@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2020-12-20, 1399/09/30

Actual recruitment start date

2020-02-29, 1398/12/10

Actual recruitment end date

2020-07-25, 1399/05/04

Trial completion date

2020-07-25, 1399/05/04

Scientific title

Evaluation of Riluzol effect as adjunctive therapy in patients with standard treatment-resistant obsessive-compulsive disorder

Public title

Riluzol effect on treatment of drug resistant obsessive obsessive compulsive disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with known obsessive compulsive disorder by DSM-V criteria. Not to use alcohol chronic. The patient had no serious risk factor for respiratory apnea and pulmonary fibrosis and not be affected. Between 18 to 65 years old The individual should be treated with a maximum dose of SSRI for at least 6 months and scored 20 or higher on the Y-BOCS criterion. The patient's liver transaminase should not be more than 5 times higher than normal.

Exclusion criteria:

Pregnancy and nursing; Patients with a history of memantine use. Patients who do not sign the ethical consent form or refuse to continue to participate in the study.

Age

To **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **32**

Actual sample size reached: **23**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization with 5 blocks will be performed for randomization of the study. The drug and placebo, which are made in exactly the same way, will be placed by the pharmacist unrelated to the research in equal packages of dark medicine with equal number, on the envelope with a label containing the information of the research center, how to use the medicine, patient number, and letters A or B will be placed for the drug group or placebo and the number will be registered in random order. The randomization tool will be statistical software that will be performed by the statistical analyzer of the study. When randomization is performed, each patient receives a code that will be recognized during the study. This code will be from 1 to 32 due to the small number of participants. The process of hiding and grouping patients and the type of medication they receive will not be disclosed to researchers.

Blinding (investigator's opinion)

Double blinded

Blinding description

Both the drug and the placebo are indistinguishable from the patients and the relevant medical staff because they are exactly the same size, shape and color. The psychiatrist, the researcher recording the patient's condition and the delivery of the drug, and the patient are not aware that the drug received is the main drug or placebo.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan Esfand St. Jundishapur University of Medical Sciences School of Pharmacy

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2020-02-02, 1398/11/13

Ethics committee reference number

IR.AJUMS.REC.1398.828

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

patient's score in Y-BOCS test

Timepoint

Before intervention, 4, 8 and 12 weeks after intervention

Method of measurement
the list of Riluzole adverse effects

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: Intervention group drug Riluzole 50 mg tablets once a day for 12 weeks
Category
Treatment - Drugs

2

Description
Control group: Placebo group 1 tablet daily for 12 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Golestan hospital
Full name of responsible person
Mohammad hosein Shiveh
Street address
Golestan Hospital, Golestan Blvd.
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2

Recruitment center
Name of recruitment center
private office of Dr Sayyah bargard
Full name of responsible person
Mohammad hosein Shiveh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of research and technology developement
Full name of responsible person
Nader Saki
Street address
Golestan Blvd., Ahvaz University of Medical Sciences, Vice Chancellor for Research and Technology Development, Ground Floor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Deputy of research and technology developement
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad hosein Shiveh
Position
Pharmacy student
Latest degree
A Level or less
Other areas of specialty/work
Medical Pharmacy
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Person responsible for scientific inquiries

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Position
Clinical pharmacy specialist, Assistant professor

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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available