Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Efficacy of Gemfibrozil as an adjusted therapy in obsessive-compulsive disorder in patients with obsessive-compulsive disorder

Protocol summary

Study aim
Determining the effect of Gem Fibrozil as an adjunctive treatment in improving the symptoms of obsessive-compulsive disorder

Design
Randomized and double-blind trial with drug control, sampling in this study will be available and by random method. 40 patients with obsessive-compulsive disorder are randomly divided into two groups. The use of web software will be provided with an electronic address. {https://www.sealedenvelope.com/simple-randomiser/v1/list}

Settings and conduct
The present study will be conducted as a randomized and double-blind clinical study with drug control. Obsessive Compulsive Disorder patients referred to Imam Hossein Shahr Karaj Hospital, diagnosed with Obsessive Compulsive Disorder during an interview with a psychiatrist, will be included in this trial by obtaining consent. The number of 60 patients with obsessive-compulsive disorder will be divided into two intervention groups (recipients of Fibrozil and sertraline) and control (sertraline only).

Participants/Inclusion and exclusion criteria
Inclusion criteria: Having DSM-V diagnostic criteria for obsessive-compulsive disorder Age between 18 and 60 years Exclusion criteria: Abuse of drugs and medicine except nicotine and caffeine The known case of Mental Retard The presence of another mental disorder in the diagnostic axis one The presence of psychotic manifestations Presence of significant medical or neurological disease (advanced kidney disease, CKD, liver disease, cardiovascular disease, and hypertension) and a history of gallstones Concomitant use of warfarin, insulin, statin drugs, niacin group drugs

Intervention groups
The intervention group (20 people) will receive Fibrozil Gem (300 mg per day) and Sertraline (100 mg per day) for 8 weeks. The control group (20 people) will receive sertraline (100 mg per day) for eight weeks.

Main outcome variables
Obsessive-Compulsive Scale - Yale-Brown Algebra

General information

Reason for update

Acronym
OCD

IRCT registration information
IRCT registration number: **IRCT20230211057389N1**
Registration date: **2023-12-10, 1402/09/19**
Registration timing: **prospective**

Last update: **2023-12-10, 1402/09/19**
Update count: **0**

Registration date
2023-12-10, 1402/09/19

Registrant information

Name
Siavash Kianmehr

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 912 461 1536

Email address
kianmehrsiavash@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-22, 1402/10/01

Expected recruitment end date
2024-04-20, 1403/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Efficacy of Gemfibrozil as an adjusted therapy in obsessive-compulsive disorder in patients with obsessive-compulsive disorder

Public title
Efficacy of Gemfibrozil as an adjust therapy in obsessive compulsive disorder, a randomized clinical trial with medication control
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having DSM-V diagnostic criteria for obsessive-compulsive disorder ages between 18 to 60
Exclusion criteria:
Abuse of drugs and medicine except nicotine and caffeine Known case of Mental Retardation Presence of other mental disorders The presence of psychotic manifestations Presence of significant medical or neurological disease (advanced kidney disease, CKD, liver disease, cardiovascular disease, and hypertension) and history of gallstones Concomitant use of warfarin Concomitant use of insulin Concomitant use of Statin group Concomitant use of niacin group drugs
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
The block randomization method with unequal block sizes will be used to allocate the samples to one of the two intervention groups and the comparison group. The randomization list will be prepared in advance using web software with an electronic address, and the researcher who is not involved in the patient selection and allocation process will have access to this form. The size of the blocks will be 2-4 and 6 {https://www.sealedenvelope.com/simple-randomiser/v1/lists}
Blinding (investigator's opinion)
Double blinded
Blinding description
In this research, blinding will be done for the patients participating in the study as well as the researcher evaluating the outcome and the researcher analyzing the data. For blinding, patients will be divided into two groups, A and B, and the randomization list will be prepared in advance with https://www.sealedenvelope.com/simple-randomiser/v1/lists using web software with an email address. Only the researcher who is not involved in the patient selection and allocation process will have access to this form. The size of the blocks will be 2, 4, and 6.
Placebo
Not used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Alborz University of Medical Science
Street address
Karaj Shahin Villa Shahrak Ibn Sina Agricultural Bank 13th Kian Building Unit 3
City
کرج
Province
Alborz
Postal code
3193747528
Approval date
2023-10-21, 1402/07/29
Ethics committee reference number
IR.ABZUMS.REC.1402.214

Health conditions studied

1

Description of health condition studied
Obsessives-Compulsive disorder
ICD-10 code
F60.5
ICD-10 code description
Obsessive-compulsive personality disorder

Primary outcomes

1

Description
Score of Yale-Brown Obsessive-Compulsive scale
Timepoint
Second, fourth and eighth week
Method of measurement
Yale-Brown Obsessive-Compulsive scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group (20 people) will receive Gemfibrozil (300 mg per day) and Sertraline (100 mg per day) for 8 weeks.
Category
Treatment - Drugs

2

Description
Control group: (20 people) will receive sertraline (100 mg per day) for eight weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Hospital, Karaj city
Full name of responsible person
Siavash Kianmehr
Street address
Karaj Shahin Villa Shahrak Ibn Sina Agricultural Bank 13th Kian Building Unit 3
City
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Email
Kianmehrsiavash@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Alborz University of Medical Science
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
Karaj University of Medical Sciences
Full name of responsible person
Siavash Kianmehr
Position
Medical Student
Latest degree
A Level or less
Other areas of specialty/work
Psychiatrics
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Karaj Shahin Villa Shahrak Ibn Sina Agricultural Bank 13th Kian Building Unit 3
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
The whole study data will be published after respecting the confidentiality of the patient's information.
When the data will become available and for how long
3 months after printing the results
To whom data/document is available
Researchers in the field of psychiatry
Under which criteria data/document could be used
Respecting the privacy of patients' information
From where data/document is obtainable
Siavash Kianmehr, a student of general medicine Email: Kianmehrsiavash@gmail.com Contact number: 09124611536
What processes are involved for a request to access data/document
A written request via email to the author of the article, which will be answered within two weeks.
Comments