

# 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

Karaj

#### Province

Alborz

#### Postal code

3193747528

#### Phone

+98 912 461 1536

#### Email

Kianmehrsiavash@gmail.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Karaj University of Medical Sciences

#### Full name of responsible person

Siavash Kianmehr

#### Street address

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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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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Karaj University of Medical Sciences

#### Full name of responsible person

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#### Position

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A Level or less

**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

Karaj University of Medical Sciences

**Full name of responsible person**

Siavash Kianmehr

**Position**

Medical Student

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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**