Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jun 2026

Effectiveness of Caffeine Augmentation in Partial-Response Obsessive Compulsive disorder Patients Treated with Selective serotonin reuptake inhibitors (SSRIs)

Protocol summary

Study aim

Efficacy of caffeine supplementation in patients with obsessive-compulsive disorder treated with Selective serotonin reuptake inhibitors (SSRIs) with partial response

Design

In this study, a phase 3, duble blind randomized controled clinical trial , 130 patients suffering from obsessive-compulsive disorder who were treated with serotonin reuptake inhibitor drugs with a random assignment software in two groups of 65 people distributed to the intervention group people who received caffeine tablets with a dose of 100 mg for one week and 200 mg in the second week and then 300 mg once a day. People in the control group will be given a placebo pill with the same form and protocol.

Settings and conduct

This double-blind study (where patients and researchers are unaware of the type of drug prescribed) will be conducted in 1405 and 1406 at Noor and Hazrat Ali Asghar Hospital in Isfahan. 130 patients with obsessive-compulsive disorder who are treated with serotonin reuptake inhibitors are divided into two groups receiving caffeine and placebo.

Participants/Inclusion and exclusion criteria

In this study, patients with obsessive-compulsive disorder who have been treated with serotonin reuptake inhibitor drugs for at least 12 weeks and who do not have psychotic thoughts addiction and do not have contraindications to opioid use are included in the study.

Intervention groups

In the intervention group, caffeine tablets with a dose of 100 mg will be given for one week, then 200 mg in the second week, and then 300 mg once a day, and placebo tablets with the same shape and protocol will be added to the control group.

Main outcome variables

Obsessive compulsive score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090801002266N23**
Registration date: **2026-05-31, 1405/03/10**
Registration timing: **registered_while_recruiting**

Last update: **2026-06-14, 1405/03/24**
Update count: **2**

Registration date

2026-05-31, 1405/03/10

Registrant information

Name

Gholamreza Kheirabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-05-22, 1405/03/01

Expected recruitment end date

2027-03-20, 1405/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effectiveness of Caffeine Augmentation in Partial-Response Obsessive Compulsive disorder Patients Treated with Selective serotonin reuptake inhibitors (SSRIs)

Public title
Evaluation of adding Cafein to SSRI in pationts with Obsessive-Compulsive Disorders

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
CD diagnosis based on clinical interview based on DSM5 clinical criteria Outpatients with at least 12 weeks (3 months) of SSRI treatment and partial response. Ability to read and write Patient consent to participate in the study

Exclusion criteria:
Pregnancy Drug abuse (based on patient report or file contents) Existence of suicidal thoughts (based on the report or content of the patient's file) The presence of psychotic symptoms based on the patient's report Diseases that can prevent the use of caffeine Taking other medications along with an SSRI, including antipsychotics, anticonvulsants, stimulants, or other augmenting medications, or taking more than one type of SSRI Excessive caffeine consumption

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **130**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization of patients between two groups is done with random assignment software. In this software, the total volume of the sample and the number of groups are entered into the software. The output of the software is a list that shows the total number of samples numerically and randomly distributed in two groups. Patients are distributed in two groups according to the time of visit and according to the mentioned list, so that the sample size reaches the required number.

Blinding (investigator's opinion)
Double blinded

Blinding description
The study was double-blind, and the researcher and the patients were unaware of the type of drug received. Allocation of drug packages to patients will be done by the pharmacist using random coding. The researchers will only receive the random code and will not know the drug or placebo content until the end of the data analysis.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Research faculty, Isfahan University of Medical Sciences, Hezar Jerib street, Isfahan, Iran

City
Isfahan

Province
Isfehan

Postal code
8434193474

Approval date
2026-02-20, 1404/12/01

Ethics committee reference number
IR.MUI.MRD.REC.1404.466

Health conditions studied

1

Description of health condition studied
Obsessive Compolsive Disorder

ICD-10 code
F42.0

ICD-10 code description
Obsessive-compulsive disorder

Primary outcomes

1

Description
Obsessive Compulsive disorder scale

Timepoint
At statrt and end of intervention

Method of measurement
With Y-BOCS questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Received Cafeine 100 mg for one week, then 200 mg cafeine for tnd week and then 300 mg cafeine for third week.
Category
Treatment - Drugs

2

Description
Control group: Received plaseboo for three weeks same to intervention group.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Noor & Ali Asghar hospital
Full name of responsible person
Gholamreza KHeirabadi
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Sponsors / Funding sources

1

Sponsor
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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
Esfahan University of Medical Sciences
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
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
The plan bellonging to goverment and we cant sharing it.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not 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