Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 2026

Evaluation of Cannabidiol effect as adjunctive therapy on symptoms of patients with Obsessive-Compulsive Disorder

Protocol summary

Study aim
Effectiveness of cannabidiol on the symptoms of patients with obsessive-compulsive disorder

Design
The clinical trial has control and intervention groups and it is a two-way blind and randomized block method.

Settings and conduct
A total of 40 patients referred to the psychiatric clinic of 22 Bahman Hospital in Qazvin are divided into two groups of intervention and control using the balance block method (Balance block randomization). Patients are asked to complete the Yale-Brown Questionnaire (YBOCS) before entering the study. intervention group received 25 mg of cannabidiol drops daily in addition to standard treatment and thecontrol groupreceived 25 mg of placebo in addition to standard treatment. Then, at weeks 4 and 8, patients are again asked to complete the Yale Brown Questionnaire to assess changes in the course of the disease.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Age more than 18 years and less than 55 years 2. The patient's physical health 3. Diagnosis of OCD based on DSM-5 criteria 4. Obtain a minimum score of 16 in the Yale-Brown Scale Questionnaire 5. Do not take any psychiatric drugs except SSRIs during the last 4 weeks 6. No previous use of cannabis or other psychotropic drugs Exclusion criteria: 1- Patient dissatisfaction 2- Having other psychiatric disorders, including cognitive disorders, psychotic disorders, drug use, etc. 3. Having physical disorders that increase the risk of side effects of the treatment 4. Pregnancy, desire to conceive and breastfeeding 5. Achieve a score above 17 of the Beck Depression Inventory before starting the project

Intervention groups
In the intervention group, in addition to normal treatment, patients are prescribed 25 mg of cannabidiol drops daily, and in the control group, in addition to normal treatment, to patients placebo will be prescribed.

Main outcome variables
Obsessive-Compulsive Scale

General information

Reason for update

Acronym
OCD

IRCT registration information
IRCT registration number: **IRCT20210310050660N1**
Registration date: **2021-04-01, 1400/01/12**
Registration timing: **prospective**

Last update: **2021-04-01, 1400/01/12**
Update count: **0**

Registration date
2021-04-01, 1400/01/12

Registrant information

Name
Mahnaz Majidi

Name of organization / entity

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Iran (Islamic Republic of)

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+98 28 3355 5054

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-04, 1400/01/15

Expected recruitment end date
2022-03-19, 1400/12/28

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Cannabidiol effect as adjunctive therapy on symptoms of patients with Obsessive-Compulsive Disorder

Public title

Evaluation of Cannabidiol effect in treatment of patients with Obsessive-Compulsive Disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Being healthy Obssesive compulsive disorder (OCD) diagnosis through DSM-5 criteria (DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS, 5TH EDITION) Achieving at least score 16 according to YALE BROWN OBSSESIVE COMPLUSIVE SCORE (YBOS) Being only on SSRIs through recent 4 weeks Do not have history of using cannabis or other ilicit drugs

Exclusion criteria:

Unwilling to participate in this study Having history of other psychiatric disorder including psychotic, cognitive and substance use disorder Being medically ill that cause more side effects than usual Pregnancy, expecting to being pregnant and lactation Achieving score more than 17 through completing Beck Depression scale before starting study

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into two treatment groups A and B using the balance block method (Balance block randomization), the size of each block is 6 and the total number of blocks is 10. Balanced randomization allocation method is used for participants in a randomized controlled clinical trial study.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients are unaware of their treatment, and medications are given in asymptomatic packages to the clinician who is not aware of the patient's treatment.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qazvin University of Medical Sciences

Street address

Deputy of research and technology, Vali-asr street

City

Qazvin

Province

Qazvin

Postal code

3415613911

Approval date

2021-02-27, 1399/12/09

Ethics committee reference number

IR.QUMS.REC.1399.502

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

Intensity of obsessive-compulsive disorder

Timepoint

Before entering into study, in week 4 and 8

Method of measurement

Yale–Brown Obsessive Compulsive Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In addition to standard treatment, 25 mg of cannabidiol drop were administered orally daily for 8 weeks.

Category

Treatment - Drugs

2

Description
Control group: In addition to standard treatment, 25 mg placebo drop were administered orally for 8 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
22 Bahman hospital ,Qazvin
Full name of responsible person
Mahnaz Majidi
Street address
22 Bahman Hospital, Parstar Alley, Rah-ahan street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Qazvin 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
Qazvin University of Medical Sciences
Full name of responsible person
Mahnaz Majidi
Position
Assistant Professor
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Latest degree
Specialist

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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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data will be available.

When the data will become available and for how long
Availability will be immediately after the publication of the article.

To whom data/document is available
The data will be available to everyone.

Under which criteria data/document could be used
All required analyzes can be performed and there will be no special conditions for access.

From where data/document is obtainable
For correspondence send Email to Dr. Majidi/ Mahnaz.majidi@yahoo.com

What processes are involved for a request to access data/document
It will reach the applicant in the shortest possible time.

Comments