

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of cannabidiol on positive symptoms in schizophrenic patients

Protocol summary

Study aim

Determining the effect of cannabidiol in improving clinical symptoms in patients with schizophrenia

Design

40 patients are randomly divided into 2 equal groups of intervention and control. The sample size is considered 20 people in each intervention and control group.

Settings and conduct

The study is designed as a randomized three-blind randomized clinical trial in which are studied 40 patients with schizophrenia hospitalized in 22 Bahman Hospital in Qazvin.

Participants/Inclusion and exclusion criteria

Patients with schizophrenia admitted to Qazvin Bahman 22 hospital. Inclusion criteria: Diagnosis of schizophrenia based on DSM-5 criteria, Candidate for treatment only with Risperidone as an antipsychotic, PANSS score greater than 60 on arrival, No cognitive impairment, No drug resistance; Exclusion criteria: Patient dissatisfaction Breastfeeding and pregnancy or desire to become pregnant within 3 months after the end of the project, Consumption of stimulants and hallucinogens and cannabis, Patients with schizophrenia without positive symptoms, Candidates for ECT.

Intervention groups

Patients receive their usual treatment (atypical antipsychotics) during the study. The intervention group is given cannabidiol drop and the control group is given a placebo.

Main outcome variables

Positive symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210310050660N2**

Registration date: **2021-04-06, 1400/01/17**

Registration timing: **prospective**

Last update: **2021-04-06, 1400/01/17**

Update count: **0**

Registration date

2021-04-06, 1400/01/17

Registrant information

Name

Mahnaz Majidi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3355 5054

Email address

m.majidi@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-10-23, 1400/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of cannabidiol on positive symptoms in schizophrenic patients

Public title

Evaluation of the effect of cannabidiol in the treatment of schizophrenic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with schizophrenia according to Diagnostic

and Statistical Manual of Mental Disorders (DSM-5) criteria Hospitalized in 22 Bahman Hospital in Qazvin Candidate for treatment only with rispidone as an antipsychotic Patient and legal guardian willingness to enter the study Positive and Negative Syndrome Scale (PANSS) score over 60 When entering the study Absence of cognitive disorders Lack of drug resistance

Exclusion criteria:
 Breastfeeding and pregnancy or desire to conceive within 3 months after completion of the plan.
 Consumption of stimulants and hallucinogens and cannabis Patients with schizophrenia without positive symptoms candidate for Electroconvulsive Therapy (ECT)

Age

No age limit

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

In this method was used from a simple randomization model of random number table and we place each participant in the intervention or control group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The drugs including cannabidiol and placebo drops, with the same shape and taste, were packaged with a label of herbarium at Alborz Pharmaceutical Company. The treating physician, researcher, and statistical analytics consulting who were all different people did not know any of the coding and content of each code; Therefore, this study was considered three-blind.

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

Street address

Dept of research Qazvin University of Medical Sciences, Valiasr Avenue

City

Qazvin

Province

Qazvin

Postal code

34199-15315

Approval date

2021-02-27, 1399/12/09

Ethics committee reference number

IR.QUMS.REC.1399.504

Health conditions studied

1

Description of health condition studied

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

Positive symptoms

Timepoint

At the beginning of the study (before the intervention) and 2, 4 and 6 weeks after the start of treatment

Method of measurement

PANSS Questionnaire Scores (Anderson Test)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Twenty patients with schizophrenia were treated with the common drug and cannabidiol drop. Patients received their present treatment (atypical antipsychotic risperidone) during the study and were matched in terms of dosage and type of antipsychotic drug. The intervention group was given cannabidiol drop (150 mg daily) for 6 weeks.

Category

Treatment - Drugs

2

Description

Control group: Twenty patients with schizophrenia were treated with common drug and placebo drops. Patients received risperidone during their usual course of treatment (atypical antipsychotic risperidone) and were matched in terms of dosage and type of antipsychotic drug. The control group was given placebo drops (150

mg daily) for 8 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

22-Bahman hospital

Full name of responsible person

Mohammad Mahdi Emam Jome

Street address

Dept of research Qazvin University of Medical Sciences, Valiasr Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin 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?

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

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Mahnaz Majidi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Position

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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

There is no more information

Study Protocol

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

Statistical Analysis Plan

Not applicable

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

Not applicable

Data Dictionary

Not applicable