Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

The efficacy of the traditional medicine preparation of dodder (Cuscuta campestris Yunck.) and polypody (Polypodium vulgare) in patients with obsessive-compulsive disorder: A double-blind clinical trial

Protocol summary

Study aim
Efficacy of traditional product of Cuscuta campestris and Polypodium vulgare in comparison with placebo in patients with OCD referred to Kerman Psychiatric Clinics in 2021-23

Design
This clinical trial study had a control group, double blind, randomized using the quadruple block method, on 84 patients.

Settings and conduct
This double-blind clinical trial is performed on patients with OCD in outpatients referring to Kerman Psychiatric Clinics in 2021-23. Patients are randomly assigned to two groups after signing the consent form and using the four-block method. 42 patients will be assigned to the traditional product group and 42 to the placebo group. Before starting treatment and after 4 to 8 weeks of taking the drug, and Yale-Brown questionnaire and quality of life will be completed.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age range 18 to 70 years Practicing obsessive compulsive disorder Be treated with Fluvoxamine No alcohol or drugs Lack of physical illnesses such as: diabetes, hypertension, cardiovascular problems A score above 21 on the Yale-Brown-OCS criterion Absence of other psychiatric disorders such as bipolar and psychotic disorders Absence of mental retardation No pregnancy or lactation Exclusion criteria: Drug intolerance Necessity to take psychiatric drugs other than fluvoxamine or to take measures such as ECT

Intervention groups
42 patients in the traditional product group (250 mg tablets of the traditional product twice a day) along with fluvoxamine tablets (daily dose of 200 mg) 42 patients in the placebo group and fluvoxamine In both groups, fluvoxamine tablets are taken at an average daily dose of 200 mg.

Main outcome variables
Severity of obsessive symptoms Quality of Life

General information

Reason for update
Changing the plant species used in herbal medicine, changing the form of herbal medicine from capsules to tablets, changing the sub-objectives of the study, changing the sample size based on the pilot study, and also changing the sampling date due to the corona epidemic.

Acronym

IRCT registration information
IRCT registration number: **IRCT20200112046092N1**
Registration date: **2020-07-11, 1399/04/21**
Registration timing: **prospective**

Last update: **2023-09-15, 1402/06/24**
Update count: **1**

Registration date
2020-07-11, 1399/04/21

Registrant information

Name
Behnaz Bakhshinejad

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 34 3213 1809

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

2021-04-09, 1400/01/20

Actual recruitment end date

2023-03-17, 1401/12/26

Trial completion date

2023-03-17, 1401/12/26

Scientific title

The efficacy of the traditional medicine preparation of dodder (Cuscuta campestris Yunck.) and polypody (Polypodium vulgare) in patients with obsessive-compulsive disorder: A double-blind clinical trial

Public title

The efficacy of the traditional medicine preparation of dodder (Cuscuta campestris Yunck.) and polypody (Polypodium vulgare) in patients with obsessive-compulsive disorde

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age range 18 to 70 years Practicing obsessive compulsive disorder Be treated with Fluvoxamine No alcohol or drugs Lack of physical illnesses such as: diabetes, hypertension, cardiovascular problems A score above 21 on the Yale-Brown-OCS criterion Absence of other psychiatric disorders such as bipolar and psychotic disorders Absence of mental retardation Non-pregnancy and lactation

Exclusion criteria:

Drug intolerance Necessity to take psychiatric drugs other than fluvoxamine or to take measures such as ECT

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **84**

Actual sample size reached: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

This study is a double-blind clinical trial on patients with obsessive-compulsive disorder in outpatients referring to Kerman psychiatric clinics in 2021-23

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double blind clinical trial. In this study, after patient consent was signed, all patients participating in this study and the clinical researcher were not aware of the type of medication given to the patient (herbal or placebo).

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Kerman University of Medical Sciences

Street address

Medical University Campus,Haft-Bagh Highway

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2020-04-27, 1399/02/08

Ethics committee reference number

IR.KMU.REC.1399.074

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

Severity of obsessive symptoms

Timepoint

Before starting the treatment and after 4 and 8 weeks of taking the drug, the participants are asked to complete the Yale-Brown questionnaire.

Method of measurement

Yale-Brown questionnaire

2

Description

quality of life

Timepoint
Before starting the treatment and after 4 and 8 weeks of taking the drug, the participants are asked to complete the quality of life questionnaire.
Method of measurement
quality of life questionnaire

Secondary outcomes

1

Description
Determining the effect of gender on the severity of obsessive symptoms and quality of life in patients with obsessive-compulsive disorders treated with fluvoxamine
Timepoint
Before starting treatment and after 4 to 8 weeks of taking the drug
Method of measurement
WHOQOL-BREF questionnaire and Yale-Brown

2

Description
Determining the effect of age on the severity of obsessive symptoms and quality of life in patients with obsessive-compulsive disorders treated with fluvoxamine
Timepoint
Before starting treatment and after 4 to 8 weeks of taking the drug
Method of measurement
WHOQOL-BREF questionnaire and Yale-Brown

3

Description
Determining the effect of education on the severity of obsessive symptoms and quality of life in patients with obsessive-compulsive disorders treated with fluvoxamine
Timepoint
Before starting treatment and after 4 to 8 weeks of taking the drug
Method of measurement
WHOQOL-BREF questionnaire and Yale-Brown

Intervention groups

1

Description
Intervention group: Herbal drug include Basfaj (Polypodium vulgare) rhizome and aftimon (Cuscuta campestris) The components of the drug are 250 mg tablets (150 mg of Besfaij rhizome powder plus 40 mg of Aftimon aqueous extract, equivalent to 150 mg of Aftimon powder), 55 mg of sucrose and 5 mg of magnesium stearate per tablet). In both groups, fluvoxamine tablets are taken with an average dose of 200 mg daily (100 mg tablets twice a day after meals). In the intervention group, in addition to fluvoxamine tablets, a 250 mg tablet containing the powdered rhizome of Besfaij and Aftimon was received twice a day (in the morning, fasting and at night at bedtime).
Category
Treatment - Drugs

2

Description
Control group: In this group, the drug used is fluvoxamine tablets with an average dose of 200 mg daily (100 mg tablets) twice a day after meals and placebo tablet. The placebo tablet contains 250 mg of cornstarch powder.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Clinic
Full name of responsible person
Behnaz Bakhshi Nejad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
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Phone
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Email
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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
Kerman 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
Kerman University of Medical Sciences

Full name of responsible person
Behnaz Bakhshi Nejad

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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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
Not applicable

Title and more details about the data/document
The data will be available upon request after publication of the article

When the data will become available and for how long
after publication of the article

To whom data/document is available
Researchers working in academic institutions

Under which criteria data/document could be used
The request is reviewed on a case-by-case basis

From where data/document is obtainable

Refer to the author's email responsible for the article

What processes are involved for a request to access data/document

The request will be answered within a maximum of two weeks

Comments