

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Effect of herbal medicine (*Cuscuta epithymum*) on clinical manifestations of patients with depression

Protocol summary

Study aim

The effectiveness of herbal medicine (*Cuscuta epithymum*) in clinical manifestations of patients with depression

Design

This study is a Phase 3 clinical trial with control group and randomization will be done using random number table. Sample size is 60

Settings and conduct

Mashhad Ebne Sina Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients at the age of 18 to 60 years with moderate depressive disorder based on DSM and tend to use herbal medicine. Non Inclusion criteria: patients with severe depression and lack of prominent medical disorder.

Intervention groups

Control group : Sertraline and placebo tablet are given in two doses in the morning and at night. Intervention group: Sertraline tablets and herbal blend is given in two doses in the morning and at night. The total study time is 6 weeks.

Main outcome variables

Depression severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171228038114N1**

Registration date: **2018-08-30, 1397/06/08**

Registration timing: **registered_while_recruiting**

Last update: **2018-08-30, 1397/06/08**

Update count: **0**

Registration date

2018-08-30, 1397/06/08

Registrant information

Name

Sanaz Negahban

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3884 8931

Email address

sanaz1370negaban@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of herbal medicine (*Cuscuta epithymum*) on clinical manifestations of patients with depression

Public title

Effect of herbal medicine on depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Detection of depression by a psychiatrist Age between 18 and 60 The tendency to use herbal medicine

Exclusion criteria:

Mild depression Depression with psychotic symptoms Pregnancy Lactation Alcohol addiction Addiction Thoughts and suicide Drug addiction Neurological

disorders

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization with random number table

Blinding (investigator's opinion)
Triple blinded

Blinding description
The participant, researcher and evaluator of research have been blind and they don't know that the drug is a placebo or the main drug.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
The Ethics Committee of Mashhad University of Medical Sciences

Street address
Central building, Daneshgah Street

City
Mashhad

Province
Razavi Khorasan

Postal code
91388-13944

Approval date
2017-11-22, 1396/09/01

Ethics committee reference number
IR.MUMS.fm.REC.1396.596

Health conditions studied

1

Description of health condition studied
Depression

ICD-10 code
F32.0

ICD-10 code description
Major depressive disorder, single episode, mild

Primary outcomes

1

Description
Severity of depression

Timepoint
At the beginning of the study, Week 6, Week 8

Method of measurement
Beck questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The herbal drug (Cuscuta epithymum) and standard dose of sertraline are given to the patient. The herbal remedy and 50 mg sertraline tablets are given twice a day For a month. Herbal medicine is provided in the form of capsule formulated in the laboratory of the Mashhad Faculty of Medicine.

Category
Treatment - Drugs

2

Description
Control group: Sertraline and placebo are given at the same dose as the intervention group. The placebo and 50 mg sertraline tablets are given twice a day For a month.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ibn Sina Hospital

Full name of responsible person
Sanaz Negahban

Street address
Ibn Sina Hospital, Horre Ameli Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad 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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Mohammad Reza Noras
Position
Assistant Professor
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Person responsible for updating data

Contact

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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

No more information

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