Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

City

Mashhad

Province

Razavi Khorasan

Postal code
919583134
Phone
+98 51 3711 2001
Email
sanaz1370negahban@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tappaghdi
Street address
Daneshgah Street
City
Mashhad
Province
Razavi Khorasan
Postal code
91388813944
Phone
+98 51 3841 3007
Email
tafaghodiM@mums.ac.ir
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
Latest degree
Ph.D.
Other areas of specialty/work
Traditional Medicine
Street address
Faculty of Iranian and Comprehensive Medicine, Ferdowsi University, Vakil Abad Blvd
City
Mashhad
Province
Razavi Khorasan
Postal code
913881-3944
Phone
+98 51 3882 9279
Email
norasmr@mums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mehdi Talebi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
Daneshgah Street
City
Mashhad
Province
Razavi Khorasan
Postal code
91388-813944
Phone
+98 38413007051
Email
talebimh@mums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Sanaze Negahban
Position
Medical student
Latest degree
Medical doctor
Other areas of specialty/work
Psychiatrics
Street address
Daneshgah Street
City
Mashhad
Province
Razavi Khorasan
Postal code
91388-13944
Phone
+98 51 3621 8474

Email
sanaz1370negahban@gmail.com

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