Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of barij deprex capsule containing Echium amoenum L and Hypericum perforatum dry extracts on mild to moderate Depression and comparison with fluoxetine

Protocol summary

Summary

Objectives: The aim of this study was to evaluate the efficacy of Barij Deprex capsule as an antidepressant in the treatment of mild to moderate depression . Design: A randomized, double-blind, single central clinical trial, in the 8-week period. Major Inclusion and Exclusion criteria: 60 patients 18-55 years old who referred to Kashan Karegarnejad Hospital with mild to moderate depression based on the Hamilton scale and clinical interview based on DSM-IV-TR criteria. Pregnancy and lactation; allergy to herbs in study; A cognitive disorder in the past year; History of bipolar disorder and other disorders Axis I(According to the SCID-I interview); Use of psychoactive medicines in the last 2 weeks; Severe medical conditions; Use of psychoactive substances; Patients with suicidal thoughts; History or use of vitamin supplements in the last 2 months are exclusion criteria. Intervention: group 1: barij deprex capsules(350 mg), BID. Group 2: fluoxetine capsules(20 mg) , BID. Main outcome variables: The severity of depression assessed by the Hamilton questionnaire and common side effect at the beginning, the fourth and eighth week of the study recorded then will be compared between the two groups and beginning of the study. Every two weeks,continue study, use medicine, the possible exclusion criteria and side effects are being investigated by telephone and the results are recorded in the questionnaire .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017082612438N24**
Registration date: **2017-09-26, 1396/07/04**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-09-26, 1396/07/04

Registrant information

Name
Mohsen Taghizadeh
Name of organization / entity
Kashan University of Medical Sciences
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Iran (Islamic Republic of)
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+98 36 1555 0021
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Recruitment status

Recruitment complete

Funding source

Barij Research Center of Medicinal plants

Expected recruitment start date

2017-06-22, 1396/04/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of barij deprex capsule containing Echium amoenum L and Hypericum perforatum dry extracts on mild to moderate Depression and comparison with fluoxetine

Public title

The effect of barij deprex capsule on Depressive

symptoms

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: 18-55 years old; patients with mild to moderate depression based on the Hamilton scale and clinical interview based on DSM-IV-TRcriteria Exclusion criteria: Pregnancy and lactation; allergy to herbs in study; A cognitive disorder in the past year; History of bipolar disorder and other disorders Axis I(According to the SCID-I interview); Use of psychoactive drugs in the last 2 weeks; Severe medical conditions; Use of psychoactive substances; Patients with suicidal thoughts; History or use of vitamin supplements in the last 2 months; Psychotic disorders

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kashan University of Medical Sciences

Street address
Medical college, Ghotb Ravandi boulevard, Kashan

City
Kashan

Postal code

Approval date
2017-05-31, 1396/03/10

Ethics committee reference number
IR.kaums.rec.1396.46

Health conditions studied

1

Description of health condition studied
Depressive episode

ICD-10 code
f32

ICD-10 code description
Depressive episode

Primary outcomes

1

Description
severity of depression

Timepoint
beginning, four and eight weeks after the start of the study

Method of measurement
Hamilton questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
control: 20 mg fluoxetine capsules daily, BID, 8 weeks

Category
Treatment - Drugs

2

Description
intervention: 350 mg barij deprex capsules, BID.8 week

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Kargarnejad Hospital

Full name of responsible person
Dr Sadeghi

Street address
Fivth of Qotb e Ravandi Blvd, Kargarnejad Hospital, Kashan

City
Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Barij Research Center of Medicinal Herbs

Full name of responsible person

Miss L.Hejazi

Street address

Km. 44 of Kashan Mashhad-e- Ardehal

City

Kashan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Barij Research Center of Medicinal Herbs

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

2

Sponsor

Name of organization / entity

Vice chancellor for research of Kashan University of Medical Science

Full name of responsible person

Dr Gholam Ali Hamidi

Street address

Medical college, Ghotb Ravandi boulevard, Kashan

City

Kashan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research of Kashan University of Medical Science

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr.M.Taghizadeh

Position

PHD

Other areas of specialty/work

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Person responsible for scientific inquiries

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Barij Research Center of Medicinal Herbs

Full name of responsible person

M.Mahlouji

Position

Clinical research Expert

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty