

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparison the effect of Echium amoenum extract with fluoxetine on depression in menopausal women.

Protocol summary

Summary

The aim of this study is to Compare the effect of Echium amoenum extract with fluoxetine on depression in menopausal women. This study is double-blind clinical trial that will be conducted on 72 menopausal women with moderate to severe depression referring to No. 7 and No. 1 health center of Ahvaz University of Medical sciences in 2017. The inclusion criteria require that the menopausal women have amenorrhea for at least 12 months; the participants age be between 45 and 60 years and Major depression criteria based on DSM-5, According to psychiatrist visit; patients with moderate to severe depression (14-22 with a test of Hamilton depression score). The exclusion criteria include: patients with depression that have suicidal thoughts; very severe depression; Sensitivity to the fluoxetine; Getting any systemic disease such as (high blood pressure; diabetes; renal disease); Taking antidepressant medication; alcohol consumption; Use of herbal medicines for treatment of menopausal symptoms; use of Drugs that interfere with fluoxetine; surgery such as hysterectomy, Vaginoplasty. The experimental group (n=36) will receive a 500mg Echium amoenum extract capsule while the control group (n=36) will be taking a 20 mg fluoxetine capsule daily for 8 weeks of intervention . The severity of depression will be measured before the intervention and in the, fourth,,sixth and eighth weeks after intervention.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2017051133925N1**

Registration date: **2017-07-18, 1396/04/27**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-07-18, 1396/04/27

Registrant information

Name

parisa yousefee baghbadorany

Name of organization / entity

Ahvaz JundiShapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3320 3202

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-02-04, 1396/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of Echium amoenum extract with fluoxetine on depression in menopausal women.

Public title

Comparison the effect of Echium amoenum extract with fluoxetine on depression in menopausal women.

Purpose

Treatment

IR.AJUMS.REC.1396.325

Inclusion/Exclusion criteria

Inclusion criteria require that the menopausal women have amenorrhea for at least 12 months; the participants age be between 45 and 60 years and Major depression criteria based on DSM-5, According to psychiatrist verdict; patients with moderate to severe depression (14-22 with a test of Hamilton depression score). The exclusion criteria include: patients with depression that have suicidal thoughts; severe depression; Sensitivity to the fluoxetine; Getting any systemic disease such as(high blood pressure;diabetes; renal disease); Taking antidepressant medication; alcohol consumption; Use of herbal medicines for treatment of menopausal symptoms; use of Drugs that interfere with fluoxetine; surgery such as hysterectomy radical women, Vaginoplasty and artificial menopause.

Age

From **45 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

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 Ahvaz JundiShapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Science and Health Services, Golestan BLV, Ahvaz

City

Ahvaz

Postal code

61357-15794

Approval date

2017-06-17, 1396/03/27

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Depression

ICD-10 code

F33.1 , F3

ICD-10 code description

Recurrent depressive disorder, current episode moderate.Recurrent depressive disorder, current episode severe without psychotic symptoms

Primary outcomes

1

Description

Depression levels

Timepoint

0 week, 4 week, 6 week, 8 week

Method of measurement

psychologist and Hamilton questioner

Secondary outcomes

1

Description

Diarrhea

Timepoint

Daily

Method of measurement

Self report

Intervention groups

1

Description

In the intervention group 500 mg Echim amoenum extract (capsule) will be administered daily for 8 week .

Category

Treatment - Drugs

2

Description

In The control group 20 mg fluoxetine (capsule) will be administered daily for 8 weeks .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Center number 7 to Ahvaz
Full name of responsible person
parisa yousefee baghbadorani, Student Of Ms Degree
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Ahvaz Jundishapur
University of Medical Science
Full name of responsible person
Doctor Behzad Sharif Makhmalzadeh
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Ground floor, Ahvaz Junishapur University of Medical
Science and Health Services of Department Research
Development and Technological, Academic city,
Ahvaz
City
Ahvaz
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, Ahvaz Jundishapur
University of Medical Science
Proportion provided by this source
100
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
ahvaz medical university
Full name of responsible person
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Person responsible for updating data

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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