Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Nov 2026

Comparison the efficacy of a combinatory product based on Echium amoenum with Citalopram in Major depressive disorder.

Protocol summary

Summary

The aim of this study is to compare the effectiveness of a combinatory product based on Echium amoenum with Citalopram in patients with depression. Patients are included in the study that have age more than 18 years old and Major depression criteria based on DSM-5, According to psychiatrist verdict. Patients are excluded with psychotic symptoms; Having a history of bipolar disorder; Having suicidal thoughts and any plans to do so; People with a history of recent emotional trauma; Patient dependence on chemical antidepressants; Pregnant and lactating women; Sensitivity to the citalopram; Sensitivity to herbal components of combinatory product; Addiction to alcohol and narcotics. Duration of this study is 8 week. Patients are allocated based on statistical software with Easy sampling method and they are enrolled in two groups of 25 people. To one group is given Citalopram pills and to other combinatory product based on Echium amoenum.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015122725710N1**
Registration date: **2016-01-25, 1394/11/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-01-25, 1394/11/05

Registrant information

Name

Mahdi Eslami

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3605 7698

Email address

eslamim3@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Mashhad University of Medical Sciences

Expected recruitment start date

2016-01-20, 1394/10/30

Expected recruitment end date

2016-06-20, 1395/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the efficacy of a combinatory product based on Echium amoenum with Citalopram in Major depressive disorder.

Public title

Comparison the efficacy of a combinatory product based on Echium amoenum with Citalopram in Major depressive disorder.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients are enrolled with age more than 18 years and major depression based on DSM-5 criteria. Exclusion criteria: Depression with psychotic symptoms; Having a history of bipolar disorder; Having suicidal thoughts and any plans to do so; People with a history of recent emotional trauma; Patient dependence

on chemical antidepressants; Pregnant and lactating women; Sensitivity to the citalopram; Sensitivity to herbal components of combinatory product; Addiction to alcohol and narcotics

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Patients are allocated based on statistical software with Easy sampling method

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Mashhad University of Medical Sciences, next to Hoveizeh cinema, Daneshgah street

City
Mashhad

Postal code

Approval date
2015-11-21, 1394/08/30

Ethics committee reference number
IR.MUMS.REC.1394.517

Health conditions studied

1

Description of health condition studied
Depression

ICD-10 code
F32.0, F32

ICD-10 code description
Mild depressive episode, Moderate depressive episode

Primary outcomes

1

Description
Sleep

Timepoint
Every 4 weeks

Method of measurement
Clinical interview

Secondary outcomes

1

Description
Depression

Timepoint
Every 4 weeks

Method of measurement
Hamilton Depression Rating Scale

Intervention groups

1

Description
Intervention group 1: One citalopram pill with 20 miligram dose every day

Category
Treatment - Drugs

2

Description
Intervention group 2: Combinatory product based on Echium amoenum in syrup form with 30 mililitre dose per day, two times a day

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ibn Sina hospital

Full name of responsible person
Dr Mahdi Eslami

Street address
Hor Ameli end of the street

City
Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Mashhad University of Medical Sciences

Full name of responsible person
Dr Mohsen Tafaghodi

Street address
Mashhad University of Medical Sciences, next to Hoveizeh cinema, Daneshgah street

City
Mashhad

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 Mashhad University of Medical Sciences

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
Mashhad University of Medical Sciences

Full name of responsible person
Dr Mahdi Eslami

Position
Ph.D. Candidate of Traditional Iranian Medicine

Other areas of specialty/work

Street address
Faculty of Traditional Medicine, East Razi street, Dah dey square

City
Mashhad

Postal code

Phone
+98 51 3853 6780

Fax

Email
eslamim3@mums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Dr Majid Anushiravani

Position
Professor Assistant of Traditional Iranian Medicine

Other areas of specialty/work

Street address
Faculty of Traditional Medicine, East Razi street, Dah dey square

City
Mashhad

Postal code

Phone
+98 51 3853 6780

Fax

Email
anushiravanim@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Dr Mahdi Eslami

Position
Ph.D. Candidate of Traditional Iranian Medicine

Other areas of specialty/work

Street address

City

Postal code

Phone
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Fax

Email

Web page address

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