

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Efficacy of a herbal syrup containing *Lavandula angustifolia* and *Cuscuta chinensis* versus citalopram in MDD with anxious distress, a double blind randomized clinical trial

Protocol summary

Summary

The aim of this investigation is to assess the efficacy of a herbal syrup containing Lavender and Chinese dodder versus Citalopram in the treatment of Major Depression, with anxious distress. This study is a six-week, single centered, double-blinded, randomized controlled trial. Fifty adult outpatients meeting the DSM- 5 criteria for mild major depression, with anxious distress will participate in the trial. Patients who have a baseline Hamilton Rating Scale for Depression score below 18 and a Hamilton Rating Scale for Anxiety score below 24 will be randomly allocated into two groups. The experimental group with 25 patients will receive Citalopram 20 mg/day and 5 cc of a placebo syrup every 12 hours. The control group with 25 patients will receive 5 cc of herbal syrup every 12 hours with a placebo tablet once a day. Patients will be assessed by a psychiatrist at baseline and by a psychiatric resident at weeks 3 and 6 after starting the medication. Efficacy will be defined as the change from baseline to endpoint in Hamilton Rating Scale scores for Depression and Hamilton Rating Scale scores for anxiety.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016102430459N1**
Registration date: **2016-12-26, 1395/10/06**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-12-26, 1395/10/06

Registrant information

Name

Toktam Sadat Firoozeei

Name of organization / entity

School of Traditional Medicine, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of a herbal syrup containing *Lavandula angustifolia* and *Cuscuta chinensis* versus citalopram in MDD with anxious distress, a double blind randomized clinical trial

Public title

Efficacy of a herbal syrup containing Lavender and Chinese dodder in the treatment of Major Depressive Disorder, with anxious distress

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. Age between 18 to 60 years old 2. Presence of Major Depressive Disorder, with anxious distress based on DSM-5 criteria 3. Scores lower than 18 in the Hamilton Rating Scale for Depression. 4. Scores lower than 24 in the Hamilton Rating Scale for Anxiety
 Exclusion criteria: 1. The presence of psychotic symptoms, current or past history of Bipolar disorder, Schizophrenia and Schizotypal personality disorder 2. Receiving psychotropic medications or any antidepressants during the past 14 days 3. The presence of an unstable disorder, Kidney or Liver failure, malignancy, Thyroid problems, Diabetes, past history of Epilepsy, bleeding disorders 4. Nursing and pregnant women, reproductive age without a contraception method 5. Substance abuse or addiction in the past 3 months 6. Suicidal tendency in the past year, scores greater than 2 on the Suicide item of the Hamilton Rating Scale for Depression 7. Women who are receiving OCP 8. Any clinically significant deterioration in the condition of the subject from baseline detected by the attending physician 9. Current or past history of Cognitive disorder in the past year 10. ECT during the past 3 months 11. Psychotherapy in the past month 12. A past history of allergy towards Lavender, Chinese dodder and Citalopram

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Central Building of Tehran University of Medical Sciences, Qods St., Keshavarz Blvd.

City

Tehran

Postal code

Approval date

2016-10-08, 1395/07/17

Ethics committee reference number

IR.TUMS.VCR.REC.1395.736

Health conditions studied

1

Description of health condition studied

Depressive episode

ICD-10 code

F32.0

ICD-10 code description

Mild depressive episode

Primary outcomes

1

Description

Severity of depression

Timepoint

Baseline, weeks 3 and 6 after starting treatment

Method of measurement

Hamilton Depression Rating Scale

Secondary outcomes

1

Description

Anxiety

Timepoint

Baseline, weeks 3 and 6 after starting treatment

Method of measurement

Hamilton Anxiety Rating Scale

Intervention groups

1

Description

Experimental group: tab citalopram 20 mg/day and 5 cc of a placebo syrup every 12 hours for 6 weeks.

Category

Treatment - Drugs

2

Description

Control group: 5 cc of herbal syrup containing lavender and Chinese dodder every 12 hours with a placebo tablet once a day for 6 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani Hospital

Full name of responsible person

Dr Toktam Sadat Firoozeei

Street address

Isfahan Province, Isfahan, Kashani Street

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School of Traditional Medicine, Tehran University of Medical Sciences, SarParast St., Taleghani St., ValiAsr Blvd.

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research, School of Traditional Medicine, Tehran University of Medical Sciences

Full name of responsible person

Dr Roja Rahimi

Street address

School of Traditional Medicine, Tehran University of Medical Sciences, SarParast St., Taleghani St., ValiAsr Blvd.

City

Tehran

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, School of Traditional Medicine, Tehran 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

School of Traditional Medicine, Tehran University of Medical Sciences

Full name of responsible person

Dr Toktam Sadat Firoozeei

Position

PhD candidate of Traditional Medicine

Other areas of specialty/work**Street address**

Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr Hossein Rezaeizadeh

Position

Assistant Professor

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Web page address

Person responsible for updating data

Contact

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