Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Efficacy of Saffron versus citalopram in the treatment of major depressive disorder, with anxious distress: A double blind randomized controlled trial.

Protocol summary

Summary

The purpose of the present investigation is to assess the efficacy of saffron versus citalopram in the treatment of major depression, with anxious distress in a six-week double-blind controlled trial. Fifty adult outpatients who meet 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 20 will be randomly allocated into two groups. Twenty five will receive citalopram 40 mg/day and 25 will receive saffron 30 mg/day. Patients were assessed by a psychiatrist at baseline and after 2, 4 and 6 weeks after the medication started. Efficacy will be defined as the change from baseline to endpoint in score on Hamilton Rating Scale for Depression and Hamilton Rating Scale for anxiety.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201501041556N71**
Registration date: **2015-01-06, 1393/10/16**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-01-06, 1393/10/16

Registrant information

Name

Shahin Akhondzadeh

Name of organization / entity

Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 5541 2222

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2015-01-21, 1393/11/01

Expected recruitment end date

2017-01-19, 1395/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Saffron versus citalopram in the treatment of major depressive disorder, with anxious distress: A double blind randomized controlled trial.

Public title

Efficacy of Saffron in the treatment of major depressive disorder, with anxious distress

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1-Presence of Major Depressive Disorder, with anxious distress based on DSM-5 criteria; 2- age between 18 to 65 years old; 3-score lower than 20 in Hamilton Rating Scale for depression. Exclusion criteria: 1-Psychotic symptoms; 2-receiving another psychotropic medications; 3-receiving any antidepressants during past one month or ECT during

past two months; 4-Presence of hypothyroidism; 5-nursing and pregnant women; 6-srious suicidality during the last year; 7-women who want to be pregnant during the future months; 8-women who are receiving OCP; 9-receiveng aspirin and anticoagulants and NSAIDs.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2-3

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
Not 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
Keshvarz Blvd

City
Tehran

Postal code

Approval date
2014-12-22, 1393/10/01

Ethics committee reference number
27225-30-03-93

Health conditions studied

1

Description of health condition studied
Major Depressive episode

ICD-10 code
F32

ICD-10 code description
Depressive episode

Primary outcomes

1

Description
Severity of anxiety

Timepoint
Baseline and weeks: 2, 4 and 6 after beginig of treatment

Method of measurement
By Hamiltion Anxiety Rating Scale

2

Description
Severity of depression

Timepoint
Baseline and weeks: 2, 4 and 6 after beginig of treatment

Method of measurement
By HamiltionDepression Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description
Cap citalopram 40 mg/day as control group for 6 weeks

Category
Treatment - Drugs

2

Description
Capsule saffron 30mg/day as intervention group for 6 weeks

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Roozbeh Hospital

Full name of responsible person
Prof. Shahin Akhondzadeh

Street address
South Kregar street, Roozbeh Hospital

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Masoud Yunesian
Street address
Tehran University of Medical Sciences, Keshvarz Blvd
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
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
Tehran University of Medical Sciences
Full name of responsible person
Prof. Shahin Akhondzadeh
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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