

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 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)

Phone

+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-serious suicidality during the last year; 7-women who want to be pregnant during the future months; 8-women who are receiving OCP; 9-receivng 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 Hamilton Anxiety Rating Scale

2

Description

Severity of depression

Timepoint

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

Method of measurement

By HamiltonDepression 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

Position

Prof. of Clinical Psychopharmacology

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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*