

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Study of administration of Saffron extracts and Fluoxetine on serum lipid profile in 40 patients with major depression.

Protocol summary

Summary

Aim: Possibility of use of Saffron as a new treatment for major depression and hyperlipidemia. Study design: double blind randomized clinical trial. Setting and conduct: This study will be carried out in a university clinic by a psychiatrist. 40 patients who fulfill the inclusion criteria will be included in the study. Patients will be randomly divided into two equal groups. Patient's depression status will be evaluated three times: once at the beginning of the study, 4 and 6 week after treatment. Experimental group will receive 15mg saffron twice a day in capsules and the control group will receive starch in capsules twice a day for 6 weeks. Same amount of Fluoxetine will be given to both groups. Inclusion criteria: diagnosed major depression; no lipid lowering medicine or depression treatment in last 6 months; informed consent; age between 18-55 years. Exclusion criteria: history of suicide; presence of chronic disease such as metabolic disease and cancer; presence of ideas of suicide Intervention: prescription of Fluoxetine and Saffron. Main outcome measures: change in depression level and serum lipid profile.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013110915334N1**
Registration date: **2013-12-25, 1392/10/04**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-12-25, 1392/10/04

Registrant information

Name

Sina Jelodar

Name of organization / entity

Shiraz university of medical science, student research committee

Country

Iran (Islamic Republic of)

Phone

+98 71 1624 8576

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jelodars@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Science, Student Research Committee

Expected recruitment start date

2012-12-04, 1391/09/14

Expected recruitment end date

2014-08-04, 1393/05/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of administration of Saffron extracts and Fluoxetine on serum lipid profile in 40 patients with major depression.

Public title

Saffron, a herbal medicine for alteration of depression and serum lipids.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: diagnosed major depression; no lipid lowering medicine or depression treatment in last 6 months; informed consent; age between 18-55 years.

Exclusion criteria: history of suicide; presence of chronic disease such as metabolic disease and cancer; presence of ideas of suicide.

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee at shiraz medical university.

Street address

Ethic committee, Shiraz university of medical science, Zand street, Shiraz, Fars, Iran.

City

Shiraz

Postal code

Approval date

2012-12-04, 1391/09/14

Ethics committee reference number

ct-p-91-4913

Health conditions studied

1

Description of health condition studied

Major depression

ICD-10 code

F32.2

ICD-10 code description

Severe depressive episode without psychotic symptoms

Primary outcomes

1

Description

Depressive status

Timepoint

at the beginning, 4th and 6th week of treatment

Method of measurement

Beck questionnaire

Secondary outcomes

1

Description

serum lipids

Timepoint

at the beginning and at the end of study

Method of measurement

laboratory

Intervention groups

1

Description

control: capsule filled with 15mg starch will be given twice a day as placebo and 20mg of Fluoxetine will be given once a day as the primary treatment.

Category

Treatment - Drugs

2

Description

Intervention: capsules containing 15mg saffron will be given twice a day and 20mg Fluoxetine will be given once a day as the primary treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

day clinic at Hafez hospital

Full name of responsible person

Ali Sahraian MD.

Street address

psychiatry ward, Hafez hospital, Chamran street, Shiraz, Fars, Iran

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shiraz University of Medical Sciences

Full name of responsible person

Golamreza Hatam

Street address

Vice chancellor for research, Shiraz University of Medical Sciences, Zand street, Shiraz, Fars, Iran.

City

Shiraz

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, Shiraz 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**

Shiraz university of medical science

Full name of responsible person

Sina Jelodar

Position

student at medical school

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

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Shiraz university of medicine, Dpt of psychiatry

Full name of responsible person

Ali Sahraian MD

Position

MD. assistant professor

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

Psychiatry ward, Hafez hospital, Chamran street, Shiraz, Fars, Iran.

City

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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