Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Study of administration of Saffron extracts and Flouxetine 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)

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+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 Flouxetine 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
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Sina Jelodar
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Ali Sahraian MD
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Other areas of specialty/work
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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