Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of saffron and fluoexetine in the treatment of mild to moderate post partum depression :A duble –blind clinical trial

Protocol summary

Summary

The purpose of the present investigation is to assess the efficacy of saffron versus fluoxetine in the treatment of major depression, with peripartum onset in a six-week double-blind controlled trial. Fifty adult outpatients who meet the DSM- 5 criteria for mild to moderate major depression, with peripartum onset will participate in the trial. Patients who have a baseline Hamilton Rating Scale for Depression score below 18 will be randomly allocated into two groups. Twenty five will receive fluoxetine 20 to 40 mg/day and 25 will receive saffron 30 mg/day. Patients were assessed by a psychiatrist at baseline and after 1, 3 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 .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201509201556N82**
Registration date: **2015-09-21, 1394/06/30**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-09-21, 1394/06/30

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

Email address

s.akhond@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2015-09-25, 1394/07/03

Expected recruitment end date

2015-11-25, 1394/09/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of saffron and fluoexetine in the treatment of mild to moderate post partum depression :A duble –blind clinical trial

Public title

Saffron in the treatment of post-partum depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Presence of Major Depressive Disorder; with peripartum onset based on DSM-5 criteria; age between 18 to 45 years old; score lower than 18 in Hamilton Rating Scale for depression. Exclusion criteria: - Psychotic symptoms or any other major psychiatric disorder; receiving any antidepressants during past one month or ECT during past two months; Presence of hypothyroidism or hyperthyrodism; srious suicidality or infanticide ideas; substance abuse or dependence uring the last three months

Age

From **18 years** old to **45 years** old

Gender
Female

Phase
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
2014-07-23, 1393/05/01

Ethics committee reference number
23220

Health conditions studied

1

Description of health condition studied
Post partum depression

ICD-10 code
F53

ICD-10 code description
Mental and behavioural disorders associated with the puerperium, not elsewhere classified

Primary outcomes

1

Description
Severity of depression

Timepoint
Baseline and weeks 2-4-6 after beginig of treatment

Method of measurement
by Hamiltion Depression Rating Scale 17-Item

Secondary outcomes

empty

Intervention groups

1

Description
Capsule fluoxetine 20 to 40mg/day as icontrol group for 6 weeks

Category
Treatment - Drugs

2

Description
Capsule saffron 15mg BID 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

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
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

Other areas of specialty/work

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Person responsible for updating data

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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