Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Saffron in the treatment of postmenopausal hot flash : a double-blind,randomised and placebo-controlled trial

Protocol summary

Summary

The aim of the study is to determine the effect of safron 30 mg/day on menopause women with moderate to severe hot flushing . Fifty women(45 to 65 years old) with moderate to severe post menopausal hot flushing will be recruited if meet the eligibility criteria. The patients will be randomly assigned into one of the following groups to receive safron 30 mg/day or placebo, for 6 weeks. The severity of symptoms,will be measured by Hot flash Related Daily Interference and Hamilton Rating Scale For Depression at the baseline and second, 4th and 6th week after the intervention. Symptoms will also be registered daily. The follow-up period will be 6 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201602031556N85**
Registration date: **2016-02-04, 1394/11/15**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-02-04, 1394/11/15

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

2016-02-20, 1394/12/01

Expected recruitment end date

2017-02-18, 1395/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Saffron in the treatment of postmenopausal hot flash : a double-blind,randomised and placebo-controlled trial

Public title

Saffron in the treatment of postmenopausal hot flash

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: women aged between 45-65 years old; menopause. Exclusion criteria: moderate to severe post-menopausal hot flushing-five episodes per day from 2 months ago; sopping of the mens from 12 month ago; receiving estrogen or progesterone during the last two months; receiving antidepressants during the last month; receving Selective Estrogen Receptor Modulators including raloxifen and tamoxifen during the last month; receiving aromatase inhibitors such as Anastrozole, Letrozole, Exemestane during the last month;receving Leuprolide acetate during the last month; receiving clonidine during the last month; receving gabapentine and pregabalin during the last month; receiving hot flushing reducing medications during the last month;

receiving amino acid supplements during the last month.

Age
From **45 years** old to **65 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
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
Tehran University of Medical Sciences, Ghods St., Keshvarz Blvd.

City
Tehran

Postal code

Approval date
2015-12-22, 1394/10/01

Ethics committee reference number
IR.TUMS.REC.1394.1666

Health conditions studied

1

Description of health condition studied
Hot flashing

ICD-10 code
N95.1

ICD-10 code description
Menopausal and female climacteric states

Primary outcomes

1

Description
Severity of hot flashing

Timepoint
Baseline and 2, 4, 6 weeks after beginnig of treatment

Method of measurement
By Hot flash Related Daily Interference

Secondary outcomes

1

Description
Severity of depression

Timepoint
Baseline and 2, 4, 6 weeks after beginnig of treatment

Method of measurement
By Hamilton Depression Rating scale

Intervention groups

1

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

Category
Treatment - Drugs

2

Description
Capsule placebo as intervention group for 6 weeks

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Roozbeh Hospital

Full name of responsible person
Dr. Shahin Akhondzadeh

Street address
Roozbeh Hospital, South Kargar Sreeet

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, Ghod St.,

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

Street address

Roozbeh Hospital, South Kargar street

City

Tehran

Postal code

Phone

+98 21 5541 2222

Fax

Email

S.akhond@sina.tums.ac.ir

Web page address

Person responsible for scientific 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

Street address

Roozbeh Hospital, South Kargar Street

City

Tehran

Postal code

Phone

+98 21 5541 2222

Fax

Email

S.akhond@sina.tums.ac.ir

Web page address

Person responsible for updating data

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

Street address

Roozbeh Hospital, South Karegar street

City

Tehran

Postal code

Phone

+98 21 5541 2222

Fax

Email

S.akhond@sina.tums.ac.ir

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