Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Saffron Vs doluxetine in the treatment of Fibromyalgia: a randomized , double blind controlled trial

Protocol summary

Summary

This study is a double blind, placebo controlled clinical trial which will be conducted in the clinic of Imam-Khomeini Hospital, Tehran, Iran. 50 patients who meet ACR criteria and inclusion criteria will be recruited. Participants randomly allocated into two groups. Twenty five will receive Duloxetine 30 mg per day during the first week and then 30 mg BID. the other group(25) will receive saffron(15 mg per day in the first week and then 15 mg BID.20 to 40 mg/day and 25 will receive saffron 30 mg/day. Patients were assessed by Breif Pain Index(BPI), Global Fatigue Index and Fibromyalgia Impact Questionnaire (FIQ) at baseline and after 2, 4 6 and 8 weeks after the medication started.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201604261556N91**
Registration date: **2016-07-26, 1395/05/05**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-07-26, 1395/05/05

Registrant information

Name
Shahin Akhondzadeh
Name of organization / entity
Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2018-02-19, 1396/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Saffron Vs doluxetine in the treatment of Fibromyalgia: a randomized , double blind controlled trial

Public title

Saffron Vs duloxetine in the treatment of Fibromyalgia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age at least 18 years old; meeting ACR criteria for Fibromyalgia; severity of pain at least 40 based on visual analogue scale. Exclusion criteria: receiving Duloxetine at present or in the past; any psychiatric disorder except for MDD; osteoarthritis, multiple sclerosis; history of multiple surgeries, infectious disease, uncontrolled endocine disease, hepatic disease, cardiovascular disease, AIDS, epilepsy, malignancy; pregnancy; nursing women; receiving serotonergic agents or MAOIs; active suicidal thoughts; abuse of alcohol or substances in the previous two years; receiving anticonvulsants, muscle relaxants, opioids, steroids, benzodiazepines in the last week; receiving thioridazine.

Age
From **18 years** old
Gender
Both

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
Tehran University of Medical Sciences, Keshvarz Blvd
City
Tehran
Postal code
Approval date
2016-06-21, 1395/04/01
Ethics committee reference number
IR.TUMS.REC.1395.114

Health conditions studied

1

Description of health condition studied
Fibromyalgia
ICD-10 code
M79.7
ICD-10 code description
Fibromyalgia

Primary outcomes

1

Description
Severity of pain
Timepoint
Baseline and weeks: 2, 4, 6 and 8 after beginig of the treatment
Method of measurement
Breif Pain Index(BPI)

2

Description
Severity of fatigue
Timepoint
Baseline and weeks: 2, 4, 6 and 8 after beginig of the treatment
Method of measurement
Global Fatigue Index

3

Description
Severity of fibromyalgia symptoms
Timepoint
Baseline and weeks: 2, 4, 6 and 8 after beginig of the treatment
Method of measurement
Fibromyalgia Impact Questionnaire(FIQ)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: capsule Duloxetine 30 mg paer day in the first week and then 30 mg BID for 7 weeks
Category
Treatment - Drugs

2

Description
Intervention group 2: capsule saffron 15 mg per day in the first week and then 15 mg BID for 7 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinic of Imam-Khomeini Hospital
Full name of responsible person
Prof. Shahin Akhondzadeh
Street address
Imam-Khomeini Hospital, Keshavarz Blvd.
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
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Prof. Shahin Akhondzadeh
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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