

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Saffron Vs duloxetine 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 Brief 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

###### 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

2016-08-22, 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 duloxetine 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 endocrine 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

**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 Kargar 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*