

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Saffron versus fluoxetine in the treatment of mild to moderate depression in post PCI patients: a double blind randomized clinical trial

#### Protocol summary

##### Summary

This randomized double-blind controlled study will be conducted in Tehran Heart Center, Tehran, Iran. Fifty post-PCI patients with a diagnosis of major depressive disorder and Hamilton Depression Rating Scale score of 14-22 will be included. Based on a random permuted block method the patients will be divided into two 25-patient groups. One group will receive Saffron Capsule with a maximum dosage of 30 mg daily and the other group will receive Fluoxetine capsule with a maximum dosage of 40 mg daily. The duration of the trial will be 6 weeks, and the patients will be assessed with Hamilton scale at baseline and at week 3 and 6. The patients will be evaluated with side-effect checklist at week 1, 3, and 6. Using t-test and repeated measure ANOVA the two groups will be compared regarding primary and secondary outcomes

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201202281556N36**

Registration date: **2012-03-01, 1390/12/11**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2012-03-01, 1390/12/11

##### 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

2012-03-05, 1390/12/15

##### Expected recruitment end date

2013-03-05, 1391/12/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Saffron versus fluoxetine in the treatment of mild to moderate depression in post PCI patients: a double blind randomized clinical trial

##### Public title

Saffron versus fluoxetine for depression in post-PCI patients

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion: 1. Patients underwent angioplasty 2. Have depression based on DSM-IV-TR and score of 14-22 on Hamilton Depression Rating Scale 3. Informed consent  
Exclusion : 1. Psychosis 2. Current use of other psychotropic agents 3. Antidepressant in the last month 4. ECT in the previous two months 5- Thyroid problem 6. Lactation and pregnancy 7. Problems in other DSM axes 8. History of substance abuse or dependence during the last three months 9. High risk of suicide 10. Oral

contraception use 11. Women of child-bearing if willing to be pregnant 12. Need for unusual psychiatric treatment

#### Age

From **20 years** old to **65 years** old

#### Gender

Both

#### Phase

2-3

#### 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

Tehran University of Medical Sciences

##### Street address

Keshavarz Boulevard

##### City

Tehran

##### Postal code

#### Approval date

2012-02-20, 1390/12/01

#### Ethics committee reference number

16074

## Health conditions studied

### 1

#### Description of health condition studied

Major Depression

#### ICD-10 code

F32

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Severity of Depressive symptoms

#### Timepoint

Weeks 0, 3 and 6

#### Method of measurement

Hamilton Depression Rating Scale-17 item

## Secondary outcomes

### 1

#### Description

Side effects

#### Timepoint

Weeks 1, 3 and 6

#### Method of measurement

Side-effect Checklist

## Intervention groups

### 1

#### Description

Saffron Capsule maximum 30 mg/day for six weeks

#### Category

Treatment - Drugs

### 2

#### Description

Fluoxetine Capsule maximum 40 mg/day for six weeks

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Tehran Heart Center

##### Full name of responsible person

Shahin Akhondzadeh

##### Street address

North Karegar Avenue

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Dr Akbar Fotouhi

##### Street address

Keshavarz Boulevard

##### 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**  
Shahin Akhondzadeh

**Position**  
Professor of clinical neuropsychopharmacology

**Other areas of specialty/work**

**Street address**  
Roozbeh hospital

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Tehran

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+98 21 6641 8466

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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**  
Shahin Akhondzadeh

**Position**  
Professor of Clinical Neuropsychopharmacology

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## Person responsible for updating data

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## 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*