

# Comparison of Crocus sativus L. and imipramine in the treatment of mild to moderate depression: a pilot double-blind randomised trial

<b>Submission date</b> 26/08/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 31/08/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 09/08/2007	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

555

# Study information

## Scientific Title

## Acronym

Saffron Project

## Study objectives

Not provided at time of registration

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Major depression

## Interventions

In this double-blind, single-centre trial, patients were randomly assigned to receive capsule of saffron 30 mg/day (10 mg three times a day [TDS]) (Group 1) and capsule of imipramine 100 mg /day (33.3 mg TDS) (Group 2) for a 6-week study.

## Intervention Type

Drug

## Phase

Not Specified

## Drug/device/biological/vaccine name(s)

Crocus sativus L., imipramine

**Primary outcome measure**

Not provided at time of registration

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/01/2002

**Completion date**

01/02/2004

## Eligibility

**Key inclusion criteria**

1. Thirty adult outpatients who met the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM IV) for major depression based on the structured clinical interview for DSM IV participated in the trial
2. Patients have a baseline Hamilton Rating Scale for Depression score of at least 18

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

30

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/01/2002

**Date of final enrolment**

01/02/2004

## Locations

**Countries of recruitment**

Iran

**Study participating centre**

**Roozbeh Psychiatric Hospital**  
Tehran  
Iran  
13337

## **Sponsor information**

### **Organisation**

Roozbeh Psychiatric Hospital (Iran)

### **Sponsor details**

South Kargar  
Tehran  
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### **Sponsor type**

Hospital/treatment centre

### **ROR**

<https://ror.org/019mzt973>

## **Funder(s)**

### **Funder type**

University/education

### **Funder Name**

Tehran University of Medical Sciences (Iran)

## **Results and Publications**

### **Publication and dissemination plan**

Not provided at time of registration

### **Intention to publish date**

### **Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**  
Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	Results	02/09/2004		Yes	No