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

Submission date	<b>Recruitment status</b> No longer recruiting	Prospectively registered	
26/08/2004		☐ Protocol	
Registration date	Overall study status	Statistical analysis plan	
31/08/2004	Completed	[X] Results	
Last Edited	Condition category	☐ Individual participant data	
09/08/2007	Mental and Behavioural Disorders		

## 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

Protocol serial number 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

## Study type(s)

Treatment

## 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(s)

Not provided at time of registration

## Key secondary outcome(s))

Not provided at time of registration

#### 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** 

## Healthy volunteers allowed

No

## Age group

**Not Specified** 

#### Sex

**Not Specified** 

## 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)

#### **ROR**

https://ror.org/019mzt973

# Funder(s)

## Funder type

University/education

## Funder Name

Tehran University of Medical Sciences (Iran)

# **Results and Publications**

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?
Results article	Results	02/09/2004		Yes	No