

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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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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