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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

Registration date
31/08/2004

Overall study status
Completed

Last Edited
09/08/2007

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] 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

Primary study design
Interventional

Study design
Randomised controlled trial

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