

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Effect of Sertraline versus Saffron capsule (SaffroMood) on the treatment of major depressive disorder in elderly: a double blind randomized clinical trial

#### Protocol summary

Registration timing: **registered\_while\_recruiting**

##### Study aim

To assess the effect of Sertraline versus Saffron capsule (SaffroMood) on the treatment of major depressive disorder in elderly

Last update: **2018-02-03, 1396/11/14**

Update count: **0**

##### Registration date

2018-02-03, 1396/11/14

##### Design

This is a double-blind randomized clinical trial, phase II, in which 50 eligible patients will be randomly assigned to the intervention and control groups using block randomization.

##### Registrant information

###### Name

Jalal Poorolajal

###### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

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+98 81 1838 0090

###### Email address

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##### Settings and conduct

The eligible elderly with the major depressive disorder who will refer to Sina Hospital during the study period will be enrolled into the trial.

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 60 to 90 years Major depressive disorder Exclusion criteria: Thyroid disorder Psychiatric disorders such as bipolar disorder and schizophrenia Drug abuse in the past 3 months Intention to suicide in the past year Using anti-depression drugs in the past month Electroconvulsive therapy in the past 2 months Using anticoagulant or NSAIDS

##### Expected recruitment start date

2018-01-20, 1396/10/30

##### Expected recruitment end date

2018-11-21, 1397/08/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Intervention groups

Intervention group: Saffron capsule (SaffroMood) 30 mg daily for 6 weeks Control group: Sertraline tablet 50 to 100 mg daily for 6 weeks.

##### Scientific title

Effect of Sertraline versus Saffron capsule (SaffroMood) on the treatment of major depressive disorder in elderly: a double blind randomized clinical trial

##### Main outcome variables

Primary outcome: Assessing the signs and symptoms of major depressive disorder before and 6 weeks after treatment using Hamilton questionnaire

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120215009014N204**  
Registration date: **2018-02-03, 1396/11/14**

**Public title**

Effect of Sertraline versus Saffron capsule (SaffroMood) on the treatment of major depressive disorder in elderly

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age of 60 to 90 years Major depressive disorder

**Exclusion criteria:**

Thyroid disorder Psychiatric disorders such as bipolar disorder and schizophrenia Drug abuse in the past 3 months Intention to suicide in the past year Using anti-depression drugs in the past month Electroconvulsive therapy in the past 2 months Using anticoagulant or NSAIDS

**Age**

From **60 years** old to **90 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **50**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The patients will be randomly assigned to intervention and control groups using block randomization.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double-blind.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Hamadan University of Medical Sciences

**Street address**

Vice-chancellor for Research and Technology,

Hamadan University of Medical Sciences, Shahid

Fahmideh Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Approval date**

2018-01-13, 1396/10/23

**Ethics committee reference number**

IR.UMSHA.REC.1396.661

**Health conditions studied****1****Description of health condition studied**

Major depressive disorder

**ICD-10 code**

F33

**ICD-10 code description**

Major depressive disorder, recurrent

**Primary outcomes****1****Description**

Assessing the signs and symptoms of major depressive disorder

**Timepoint**

Before and 6 weeks after treatment

**Method of measurement**

Using Hamilton questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Saffron capsule (SaffroMood) 30 mg daily for 6 weeks

**Category**

Treatment - Drugs

**2****Description**

Control group: Sertraline tablet 50 to 100 mg daily for 6 weeks.

**Category**

Treatment - Drugs

**Recruitment centers**

## 1

### Recruitment center

**Name of recruitment center**

Sina Hospital

**Full name of responsible person**

Dr Fatemeh Ramazan Shams

**Street address**

Sina Hospital, Mirzadeh Eshghi Ave.

**City**

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**Province**

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**Postal code**

6517838695

**Phone**

+98 81 3827 4184

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frsshams@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr Saeid Bashirian

**Street address**

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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info.research@umsha.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Hamedan University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

Academic

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr Fatemeh Ramazan Shams

**Position**

Resident of Psychiatry

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Psychiatrics

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Sina Hospital, Mirzadeh Eshghi Ave.

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr Ali Ghaleiha

**Position**

Psychiatrist

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Psychiatrics

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr Jalal Poorolajal

**Position**

Professor of Epidemiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

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**Email**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available