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

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

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.

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.

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

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.

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**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-03, 1396/11/14**
Update count: **0**

Registration date
2018-02-03, 1396/11/14

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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Recruitment status
Recruitment complete

Funding source

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

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

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.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Dr Jalal Poorolajal

Position
Professor of Epidemiology

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Epidemiology
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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