Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Evaluation of the effects of standardized hydroalcoholic extract of rosemary (Rosmarinus officinalis L.) capsule as adjunctive treatment in major depressive disorder

Protocol summary

Study aim
Evaluation of the effects of standardized hydroalcoholic extract of rosemary (Rosmarinus officinalis L.) capsule as adjunctive treatment in major depressive disorder

Design
This study is a randomized, double-blind, controlled clinical trial with a parallel group design of 44 patients.

Settings and conduct
Patients are selected from Kerman Baysat Clinic. Participants and physicians are blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Outpatient with Major Depression Based on DSM-5 Criterion, 18-55 years old, depressed patient who has never been on medication and is a candidate for SSRI treatment. Exclusion criteria:Pregnancy, lactation, having underlying medical or psychiatric illnesses, hypersensitivity reactions to rosemary, people at high risk of suicide, mental retardation - dependence on a variety of substances

Intervention groups
The treatment group receives one capsule daily (each capsule containing about 500 mg of extract) for 8 weeks and the control group receives the same placebo in terms of shape, color, and packaging with the same dose of the treatment group.

Main outcome variables
Anxiety and depression are measured using the Hospital Anxiety Depression Scale and Beck Depression Inventory second edition questionnaires at baseline, 4 weeks and 8 weeks later.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110310006026N11**
Registration date: **2019-11-07, 1398/08/16**
Registration timing: **prospective**

Last update: **2019-11-07, 1398/08/16**
Update count: **0**

Registration date
2019-11-07, 1398/08/16

Registrant information

Name
Fatemeh Dabaghzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 34 3132 5034

Email address
dabaghzadeh@razi.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-11-11, 1398/08/20

Expected recruitment end date
2021-11-11, 1400/08/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effects of standardized hydroalcoholic extract of rosemary (Rosmarinus officinalis L.) capsule as adjunctive treatment in major depressive disorder

Public title

Evaluating the effects of rosemary capsule as adjunctive treatment in major depressive disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Outpatient with Major Depression Based on DSM-5 Criterion, 18-55 years old, depressed patient who has never been on medication and is a candidate for SSRI treatment.

Exclusion criteria:

Pregnancy, lactation, having underlying medical or psychiatric illnesses, hypersensitivity reactions to rosemary, people at high risk of suicide, mental retardation - dependence on a variety of substances

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

The eligible participants are allocated to one of the two study groups in a 1:1 ratio. Allocation is by block randomization with a block size of four. A person (not involved in the trial) generates allocation sequence.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and physician: rosemary and placebo capsules had the same shape, color and outer packaging.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

Beginning of Jahad Blvd., Tahmasebad Fourways

City

Kerman

Province

Kerman

Postal code

7619813159

Approval date

2019-10-14, 1398/07/22

Ethics committee reference number

IR.KMU.REC.1398.359

Health conditions studied

1

Description of health condition studied

major depressive disorder

ICD-10 code

F06.32

ICD-10 code description

Mood disorder due to known physiological condition with major depressive-like episode

Primary outcomes

1

Description

Anxiety

Timepoint

At the beginning of the study and ,the fourth and eight weeks after the beginning of the study

Method of measurement

Hospital Anxiety Depression Scale (anxiety sub-scale)

2

Description

Depression

Timepoint

At the beginning of the study and ,the fourth and eight weeks after the beginning of the study

Method of measurement

Beck Depression Inventory second edition

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: One capsule daily (each capsule containing about 500 mg of extract) for 8 weeks

Category

Treatment - Drugs

2

Description

Control group:They receive one 500 mg capsules of

placebo daily for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat clinic

Full name of responsible person

Fatemeh Dabaghzadeh

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Besat clinic, Tahmasb abad Ave, Kerman, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

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

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Fatemeh Dabaghzadeh

Position

Clinical pharmacist

Latest degree

Ph.D.

Other areas of specialty/work

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Email

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

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