

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Evaluation of adjunctive therapy of propolis in the treatment of mild to moderate depression

Protocol summary

Formulation and production of a new oral form of Propolis
Write an ISI research article

Study aim

Extraction and preparing an oral dosage form of propolis
Evaluation of the depression score in the control group
Evaluation of the depression score in the treated group
Comparison of the depression score in the control and intervention group

Design

First phase: primary visit and examination Second phase: visit and examination after weeks 1, 4 and 6
1- Drug group: The patients will take a SSRI drugs with Propolis (2000mg/70 kg) during 6 weeks. 2- Placebo group: The patients will take a SSRI drugs with placebo during 6 weeks.

Settings and conduct

Drug formulation will be done in Institute of Medicinal Plants. Clinical phase will be executed in psychiatrist's office. According to literature we consider 68 patients that Stratified Randomly divided in control and study groups of 68 persons. Randomization will be done due to overcoming conflicts. Blinding: Drug and placebo capsules have same size (00), color and weight. Both will be packed similarly with two codes A & B. Except project implementer else person Will not know drug codes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: individuals with diagnosis of mild-moderate depression according HDRS score Age between 18-25 Outpatient Exclusion criteria: Diagnosis of another non-depression disorder for patient during study Suicide inclination The patient receive an antidepressant medication except SSRI impossibility to track patient Occurrence of side effects fever, digestive and heart complications followed by treatment

Intervention groups

The patients will divided into two groups randomly: first group take SSRI with 1g Propolis and second group will take same dosage of SSRI with placebo. HDRS questionnaire score will be examined by psychiatrist in 0, 2, 4 and 6 weeks after start of study.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170311033004N2**

Registration date: **2018-08-29, 1397/06/07**

Registration timing: **prospective**

Last update: **2018-08-29, 1397/06/07**

Update count: **0**

Registration date

2018-08-29, 1397/06/07

Registrant information

Name

Ali Razmi

Name of organization / entity

Academic Center for Education, Culture and Research

Country

Iran (Islamic Republic of)

Phone

+98 26 3476 4015

Email address

arazmi@alumnus.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-01, 1397/07/09

Expected recruitment end date

2021-03-20, 1399/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Evaluation of adjunctive therapy of propolis in the treatment of mild to moderate depression

Public title
Propolis effects on depressive disorder

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Individuals with diagnosis of mild-moderate depression according HDRS score Age between 18-25 Outpatient Patients with no comorbid disorders diabetes, high blood pressure or cardiovascular disease Patients with no comorbid mental condition No consumption drugs other than SSRI Non-pregnant

Exclusion criteria:

Diagnosis of another non-depression disorder for patient during study Suicide inclination Taking anti depression medication except SSRI or electroconvulsive therapy impossibility to track disease (absence at the time of visit, cancellation of the continuation of the study and death) Occurrence of allergic reaction Occurrence of some side effect disorders such as fever, digestive and heart complications due to drug intake Hospitalization

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **68**

Randomization (investigator's opinion)
Randomized

Randomization description
A stratified randomization and Four unit blocks (AABB, ABAB, ABBA & etc.) will be used. The selected stratifies are gender and the used medications. SAS software will perform the randomization process.

Blinding (investigator's opinion)
Double blinded

Blinding description
Placebo and the extract will filled in the same size (00) and same color capsules. The additive filler be applied to make same weight for the both. Only the main applicant are aware about the content of the pills.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Avicenna Biomedical Research Ethics Committee

Street address

Darakeh street, Shahid Beheshti university

City

Tehran

Province

Tehran

Postal code

1983963113

Approval date

2018-06-24, 1397/04/03

Ethics committee reference number

IR.ACECR.Avicenna.REC.1396.30

Health conditions studied

1

Description of health condition studied

Depression

ICD-10 code

F32.0, F32

ICD-10 code description

Depressive episode In typical mild, moderate, or severe depressive episodes, the patient suffers from lowering of mood, reduction of energy, and decrease in activity. Capacity for enjoyment, interest, and concentration is reduced, and marked tiredness

Primary outcomes

1

Description

Formulation and primary sample

Timepoint

6 months

Method of measurement

quantitative

Secondary outcomes

1

Description

clinical trials

Timepoint

22th month

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: Patients in this group will take a SSIRs anti-dep resion medicine with Propolis (2000mg/70kg) during 6 weeks

Category

Treatment - Drugs

2

Description

Control group: This group receives the previously prescribed medications and capsules contains placebo (lactose and breadcrumbs as fillers).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh hospital

Full name of responsible person

Ali Razmi

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District 11, Karegar St, No. 606

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Academic Center for Education, Culture and Research (ACECR)

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Web page address

http://acecr.ac.ir

Grant name

Grant code / Reference number

396000000

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Academic Center for Education, Culture and Research (ACECR)

Proportion provided by this source

100

Public or private sector

Private

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

Academic Center for Education, Culture and Research (ACECR)

Full name of responsible person

Ali Razmi

Position

Pharmacology phd

Latest degree

Ph.D.

Other areas of specialty/work

Pharmacology

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Latest degree

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Web page address**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

Results of this project will be published as an article and no individual data sharing is applicable.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

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

Title and more details about the data/document

Study protocol, statistical analysis plan, informed consent form and clinical study report will be available deidentified for other researchers .

When the data will become available and for how long

Immediately following publication; no end date

To whom data/document is available

Anyone

Under which criteria data/document could be used

The data is available for any analysis including reviews and meta-analyses.

From where data/document is obtainable

Data are available on the website of the journal which published the paper. Also the mentioned data be available by contacting email
arazmi@alumnus.tums.ac.ir .

What processes are involved for a request to access data/document

Proposals should be directed to
arazmi@alumnus.tums.ac.ir. To access, data requestors will need send sign a data access agreement.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Institute of Medicinal Plants (ACECR)

Full name of responsible person

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Position

Pharmacology/PhD

Latest degree

Ph.D.

Other areas of specialty/work

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