Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the additive effect of silymarin in the treatment of patients with moderate depression

Protocol summary

Study aim
Additive effects of silymarin on patients with moderate depression symptoms referred to Ibn-e-Sina Hospital, Mashhad

Design
A Randomized, Double-Blind, Placebo-Controlled Clinical Trial

Settings and conduct
Patients referred to Ibn-e-sina hospital- Mashhad- Iran, after signing informed consent, will be randomly allocated to the following two groups. Placebo Group in which, patients (n=40) will receive placebo tablets twice a day and silymarin Group in which, patients (n=40) will receive silymarin 140 mg, twice a day, for 8 weeks. All subjects will receive the conventional depression therapy during study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: (1)Patients with moderate depression, (2) Being 20-50 years old, (3) Patient consent to participate in the study, (4) Not having specific physical (e.g. cancer, Acquired immunodeficiency syndrome (AIDS), Multiple Sclerosis (MS)) or mental illness, (5) Not having allergic to silymarin, (6) Not being pregnant/breast feeding. Exclusion criteria: (1) Lack of patient cooperation in silymarin consumption, (2) Having allergic reaction or intolerable side effect caused by silymarin

Intervention groups
(1) Placebo Group in which, patients (n=40) will receive placebo tablets twice a day, for 8 weeks. (2) Silymarin Group in which, patients (n=40) will receive silymarin 140 mg, twice a day, for 8 weeks.

Main outcome variables
Beck Depression Inventory (BDI) questionnaire and General Health Questionnaire (GHQ) will be completed before treatment (day 0) and at the end of weeks 4 and 8 after starting treatment.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160804029191N4**
Registration date: **2021-12-11, 1400/09/20**
Registration timing: **prospective**

Last update: **2021-12-11, 1400/09/20**
Update count: **0**

Registration date
2021-12-11, 1400/09/20

Registrant information

Name
Vahideh Ghorani Sirjani

Name of organization / entity
Mashhad University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 51 3882 8565

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ghoranisv921@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-01-21, 1400/11/01

Expected recruitment end date
2022-07-21, 1401/04/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the additive effect of silymarin in the treatment of patients with moderate depression

Public title
Effect of silymarin in the treatment of patients with depression

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with moderate depression Being 20-50 years old Patient consent to participate in the study Not having specific physical (e.g. cancer, Acquired immunodeficiency syndrome (AIDS), Multiple Sclerosis (MS)) or mental illness Not having allergic to silymarin Not being pregnant/breast feeding

Exclusion criteria:
Lack of patient cooperation in silymarin consumption Having allergic reaction or intolerable side effect caused by silymarin

Age
From **20 years** old to **50 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization method (using https://www.Randomization.com-generated sequence) In this method, using website https://www.Randomization.com that generates the random number sequences, the random number sequences are determined for the required sample size (n=40 in each group). Following, after patients enter the study based on the inclusion criteria, according to the list of the random number sequences generated, individuals are assigned to one of the intervention and placebo groups, and this continues until the number of patients in each group is completed.

Blinding (investigator's opinion)
Double blinded

Blinding description
Drugs will be packed and labelled. No information on the randomization schedule or the contents of drug packs will be available to patients, investigators, care providers and outcomes assessors and they will be blinded. The patients will be blinded in the sense that they do not know whether they were receiving the placebo or silymarin. They randomly assign to one of the two groups. Outcomes assessors shall be blinded as to what group the patient belongs to. One person in the project who does not belong to any of the groups of patients, investigators, care providers and outcomes assessors, will oversee on blinding method.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences

Street address
Ghoreshi department, Daneshgah St.

City
Mashhad

Province
Razavi Khorasan

Postal code
13944-91388

Approval date
2021-08-10, 1400/05/19

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1400.443

Health conditions studied

1

Description of health condition studied
Depression

ICD-10 code
F32.1

ICD-10 code description
Major depressive disorder, single episode, moderate

Primary outcomes

1

Description
Beck Depression Inventory (BDI) questionnaire

Timepoint
Before treatment (day 0) and at the end of weeks 4 and 8 after starting treatment

Method of measurement
Completion of the questionnaire by patient or researcher

2

Description
General Health Questionnaire (GHQ)

Timepoint
Before treatment (day 0) and at the end of weeks 4 and 8 after starting treatment

Method of measurement
Completion of the questionnaire by patient or researcher

Secondary outcomes

empty

Intervention groups

1

Description
Placebo Group in which, patients (n=40) will receive placebo tablets twice a day, for 8 weeks.
Category
Treatment - Drugs

2

Description
Silymarin Group in which, patients (n=40) will receive silymarin 140 mg, twice a day, for 8 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ibn Sina Hospital, Mashhad
Full name of responsible person
Maedeh Kamrani
Street address
Ibn Sina Hospital, Horr-e-Ameli St.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Maedeh Kamrani
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
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Position
Assistant Professor
Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for updating data

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Position

Ph.D.

Latest degree

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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

Dr. Vahideh Ghorani is committed to presenting all the achievements of the project in accordance with the framework of Mashhad University of Medical Sciences.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available