

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The Effect of Bombyx Mori Syrup - An Iranian Traditional Medicine Preparation - on Mild to Moderate Depression and Anxiety: a Triple-Blind Randomized Clinical Trial

Protocol summary

Study aim

The effect of bombyx mori syrup, an Iranian medicine preparation, on mild to moderate depression and anxiety.

Design

Patients were divided into control and intervention groups using block randomization model and were distributed in a three-blind study of Bombyx mori syrup and sertraline, without mentioning the name of the drug. The study duration for both groups will be 12 weeks. The sample size for each group will be 30 people.

Settings and conduct

This study is a triple blind randomized clinical trial. The sample of the study included patients with depression and anxiety who referred to the Urmia University of Medical Sciences Specialized Psychiatric Clinic in 2019. Beck Depression Inventory and Beck Anxiety Inventory will be completed with patient information questionnaire. The study group received Bombyx mori syrup with Sertraline and the control group received Sertraline with Bombyx mori syrup placebo for 12 weeks. Patients will be followed up at 6 and 12 weeks and data will be analyzed.

Participants/Inclusion and exclusion criteria

Age range 18-60 years; at least two weeks of symptoms of depression and anxiety; no other mental illnesses; lack of physical disorders such as cancer, AIDS, diabetes, liver failure; Female patients; mild to moderate score from Beck Depression Inventory and Beck Anxiety Inventory

Intervention groups

The intervention group will be prescribed Bombyx mori syrup with sertraline and the control group will be given Bombyx mori syrup and sertraline for 12 weeks. Bombyx mori syrup will be given twice a day. Sertraline tablets will be given to both groups at a dose of 50mg.

Main outcome variables

Bombyx mori syrup effects on depression and anxiety

symptoms of patients; depression and anxiety score of patients before and after Drugs change significantly; depression score and anxiety score of patients before and after Bombyx mori syrup and sertraline significantly.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190724044320N1**

Registration date: **2019-09-04, 1398/06/13**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-04, 1398/06/13**

Update count: **0**

Registration date

2019-09-04, 1398/06/13

Registrant information

Name

yahya zeynalpour fattahy

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3338 0126

Email address

yahya.zeynalpour@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Bombyx Mori Syrup - An Iranian Traditional Medicine Preparation - on Mild to Moderate Depression and Anxiety: a Triple-Blind Randomized Clinical Trial

Public title
The Effect of Bombyx Mori Syrup - An Iranian Traditional Medicine Preparation - on Depression and Anxiety

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 and 60 years MADD for two weeks
Beck's Depression score: 14-28 Beck's Anxiety score: 8-25

Exclusion criteria:
Age
From **18 years** old to **60 years** old

Gender
Both

Phase
0

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be divided in two control and

Blinding (investigator's opinion)
Triple blinded

Blinding description
Researcher,

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1
Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical

Sciences
Street address
University of Red Crescent - front of tax organization - kashani Ave. - Urmia
City
Urmia
Province
West Azarbaijan
Postal code
5715654868

Approval date
2019-01-09, 1397/10/19
Ethics committee reference number
IR.TUMS.VCR.REC.1397.739

Health conditions studied

1
Description of health condition studied
Depression and Anxiety
ICD-10 code
F41.2
ICD-10 code description
Mixed anxiety and depressive disorder

Primary outcomes

1
Description
Beck Depression Inventory score
Timepoint
Assessment of Beck Depression Inventory at baseline, 6 and 12 weeks after drug administration
Method of measurement
Beck Depression Inventory

2
Description
Beck Anxiety Inventory score
Timepoint
Assessment of Beck Anxiety Inventory at baseline, 6 and 12 weeks after drug administration
Method of measurement
Beck Anxiety Inventory

Secondary outcomes

empty

Intervention groups

1
Description
Intervention group: The intervention group will be prescribed Bombyx Mori syrup with Sertraline tablets for 12 weeks. Bombyx Mori syrup will be given 5 cc (3grams) twice a day and Sertraline tablets will be administered at a dose of 50 mg daily. Sertraline are produced by Sobhan

Pharmaceutical Company and Bombyx Mori syrup is manufactured by the Faculty of Pharmacy, Tehran University of Medical Sciences.

Category

Treatment - Drugs

2**Description**

Control group: The control group will be prescribed sertraline tablets with Bombyx Mori syrup placebo for 12 weeks. Bombyx Mori syrup placebo will be given 5 cc (3grams) twice a day and Sertraline tablets will be administered at a dose of 50 mg daily. Sertraline are produced by Sobhan Pharmaceutical Company and Bombyx Mori syrup placebo is manufactured by the Faculty of Pharmacy, Tehran University of Medical Sciences.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Urmia University of Medical Sciences

Full name of responsible person

Yahya Zeinalpour Fattahi

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Tadbir Clinic, Ammar street, Urmia

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Hossein Rezaizadeh

Street address

No. 27, North Sarparast Street, between Vesal and Palestine, West Taleghani Street, Tehran

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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

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Yahya Zeinalpour Fattahi

Position

Assistant of Iranian traditional medicine

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Person responsible for updating data

Contact

Name of organization / entity

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Email

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

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

According of the rules of the faculty of Iranian traditional medicine of Tehran university of medical sciences

When the data will become available and for how long

Up to two years after the end of the study

To whom data/document is available

Researchers in academic and scientific institutions according of the rules of the Faculty of Iranian traditional medicine of Tehran university of medical sciences

Under which criteria data/document could be used

According of the rules governing scientific articles

From where data/document is obtainable

Faculty of Iranian traditional medicine of Tehran university of medical sciences and responsible for scientific accountability of the study

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

According of the rules governing scientific articles

Comments

This study is a thesis approved by the faculty of Iranian medicine of Tehran university of medical sciences and it is subject to its laws regarding any publication, exploitation and other legal benefits.