

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

: The effect of curcumin supplementation as adjunctive therapy in the treatment of patients with bipolar disorder-Depression

Protocol summary

Study aim

The main goal: Determining the effect of curcumin supplementation in the treatment of patients with bipolar depression Specific goals: 1. Determining the average score of the questionnaire of the groups before and after the intervention 2. Comparison of the average scores of the questionnaire groups before and after the intervention based on the age of the patients 3. Comparison of the average scores of the questionnaire groups before and after the intervention based on the gender of the patients 4. Comparison of the average score of the questionnaire of the groups before and after the intervention based on the history of the disease

Design

A randomized controlled clinical trial

Settings and conduct

5 Azar Hospital in Gorgan in 1402-1403

Participants/Inclusion and exclusion criteria

Criteria for entering the study: 1. Consent of the patient or the patient's guardian to participate in the study 2. Diagnosing a patient's bipolar depression disorder by a psychiatrist based on V-DSM criteria 3. Age over 18 years Exclusion criteria: 1. Other psychiatric disorders 2. Chronic inflammatory diseases 3. Taking herbal medicines 4. History of allergy to herbal medicines and turmeric 5. Pregnancy or breastfeeding 6. Patients taking anticoagulant and antiplatelet drugs such as aspirin, clopidogrel, heparin, enoxaparin, warfarin

Intervention groups

Group A: two 500 mg curcumin supplements daily for 6 weeks, in addition to the previous usual medications Group B: The same drug treatment for 6 weeks The safe dose for curcumin is 500 to 1000 mg per day, for this reason, the dose of 1000 mg was chosen.

Main outcome variables

The effectiveness of the treatment is the main outcome of this study that will be measured with the questionnaire. The questionnaire will be completed for patients before and after the intervention. The difference

in the questionnaire score will be considered the treatment effect.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231206060281N1**

Registration date: **2023-12-14, 1402/09/23**

Registration timing: **prospective**

Last update: **2023-12-14, 1402/09/23**

Update count: **0**

Registration date

2023-12-14, 1402/09/23

Registrant information

Name

Azadeh Maghsoudlou rad

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-16, 1402/09/25

Expected recruitment end date

2024-06-20, 1403/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

: The effect of curcumin supplementation as adjunctive therapy in the treatment of patients with bipolar disorder-Depression

Public title

: The effect of curcumin supplementation as adjunctive therapy in the treatment of patients with bipolar disorder-Depression

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Consent of the patient or the patient's guardian to participate in the study Diagnosing a patient's bipolar depression disorder by a psychiatrist based on V-DSM criteria Age over 18 years

Exclusion criteria:

Other psychiatric disorders Chronic inflammatory diseases Taking herbal medicines History of allergy to herbal medicines and turmeric Pregnancy or breastfeeding Patients taking anticoagulant and antiplatelet drugs such as aspirin, clopidogrel, heparin, enoxaparin, warfarin

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, people will be divided into two groups by random block method. First, we will check the initial score of the BDRS questionnaire of the people and put all 4 people with almost the same questionnaire score in one block. Then we will choose a block from the following blocks by a simple random method with replacement and based on the permutation of letters in that block, the patients will receive the treatments. 1. ABBA 2. AABB 3. BAAB 4. BABA 5. BBAA 6. ABAB

Blinding (investigator's opinion)

Single blinded

Blinding description

This study will be conducted in a single-blind manner, and the neuropsychological assistants will not be involved in the type of treatment the patients will receive. Each patient's treatment type will be delivered inside identical envelopes to conceal random allocation and prevent guessing. To maintain blinding, drugs will be delivered to patients by another research team member (other than the neuropsychiatric assistant).

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Golestan University of Medical Sciences

Street address

Department of Neurology and Psychiatry, 5 Azar Hospital, 5th Azar Street, Gorgan

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Province

Golestan

Postal code

4934174515

Approval date

2023-11-14, 1402/08/23

Ethics committee reference number

IR.GOUMS.REC.1402.371

Health conditions studied**1****Description of health condition studied**

Bipolar disorder

ICD-10 code

F31

ICD-10 code description

Bipolar disorder

Primary outcomes**1****Description**

The effectiveness of the treatment is the main outcome of this study that will be measured with the questionnaire. The questionnaire will be completed for patients before and after the intervention. The difference in the questionnaire score will be considered the treatment effect.

Timepoint

The beginning and end of the study

Method of measurement

the Persian Version of Bipolar Depression Rating Scale

Secondary outcomes

1

Description

Measurement of drug side effects

Timepoint

End of week 6 and 12. In order for the doctor to ensure that the conditions of all patients are the same and to control the effects of treatment with standard drugs, all patients will receive the usual standard treatment for 6 weeks. Then, before dividing the patients into two groups and starting the intervention, the questionnaire will be completed by the assistant psychiatrist. Then the patients will be randomly divided into two groups and will receive the assigned treatment for 6 weeks. The questionnaire will be completed again for them.

Method of measurement

Standard questionnaire

Intervention groups

1

Description

Intervention group: In addition to the previous usual drugs (sodium valproate and risperidone or olanzapine or ketamine), they will receive 2 tablets of curcumin 500 mg daily for 6 weeks.

Category

Treatment - Drugs

2

Description

Control group: They will continue the same drug treatment as before for 6 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

5 Azar Hospital, Gorgan

Full name of responsible person

Dr. Leila Kashani

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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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Kilometer 5 of the Gorgan-Kordkoy road, at the beginning of Shasat Kala Road, the Philosophical Higher Education Complex of Golestan University of Medical Sciences, the Vice-Chancellor for Research and Technology

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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

Gorgan 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

Gorgan University of Medical Sciences

Full name of responsible person

Dr. Azadeh Maqsoodlou Rad

Position

Resident

Latest degree

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Other areas of specialty/work

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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

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

Not applicable

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

The files related to all of the above will be loaded on the journal site at the time of publication of this article.

When the data will become available and for how long

After publishing the article

To whom data/document is available

All those who send an email to the author of the article and request the data.

Under which criteria data/document could be used

All those who send an email to the author of the article and request the data.

From where data/document is obtainable

All those who send an email to the author of the article and request the data.

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

All those who send an email to the author of the article and request the data.

Comments