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 bipolardisorder-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

Country

Iran (Islamic Republic of)

Phone

+98 911 275 2459

Email address

azadeh_rad1990@goums.ac.ir

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 bipolardisorder-Depression

Public title
: The effect of curcumin supplementation as adjunctive therapy in the treatment of patients with bipolardisorder-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

City
Gorgan

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
Street address
5 Azar Hospital, Panj-E-Azar Street, Gorgan
City
Gorgan
Province
Golestan
Postal code
4934174515
Phone
+98 17 3222 0561
Email
azadeh_rad1990@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Dr. Narges Begum Mirbehbahani
Street address
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
City
Gorgan
Province
Golestan
Postal code
4934174515
Phone
+98 17 3245 1660
Email
azadeh_rad1990@yahoo.com
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
Medical doctor
Other areas of specialty/work
Psychiatrics
Street address
Department of Neurology and Psychiatry, 5 Azar Hospital, Fifth Azar Street, Gorgan
City
Gorgan

Province
Golestan
Postal code
4937195763
Phone
+98 17 3245 1660
Email
azadeh_rad1990@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Dr. Azadeh Maghsoudloo Rad
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Psychiatrics
Street address
Hospital 5Azar Panj-E-Azar Street Gorgan
City
Gorgan
Province
Golestan
Postal code
4934174515
Phone
+98 17 3222 0561
Email
azadeh_rad1990@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Dr. Azadeh Maghsoudloo Rad
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Psychiatrics
Street address
Hospital 5 Azar Panj-E-Azar Street Gorgan
City
Gorgan
Province
Golestan
Postal code
4934174515
Phone
+98 17 3222 0561
Email
azadeh_rad1990@yahoo.com

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