Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluating the Effect of Probiotics Augment in Treatment of Bipolar Disorder.

Protocol summary

Study aim
Study of the effect of probiotics on the treatment of patients with type 1 bipolar disorder.

Design
Clinical trials with a group of intervention and control, with a size of 30 people in each group, community-based and pragmatic, with parallel, blind, randomized groups.

Settings and conduct
Patients with type 1 bipolar disorder who referred to Behshati hospital in Kerman are randomly assigned to two groups A and B. Participants in the study, the person who analyzed the data and also the researcher Idols are not aware of these codes.

Participants/Inclusion and exclusion criteria
All patients with type 1 bipolar disorder referring to Kerman's Shahid Beheshti Hospital, aged 18 to 65 years old, who changed their dose of antipsychotics, lithium and valproate two weeks before entering the study, as well as during treatment. Do not enter this study. Pregnant and lactating women, patients with history of lactose susceptibility, chronic heart, lung, kidney, liver, patients with history of supplements, probiotics in the last two months, patients with schizophrenia, and patients with a history of seizure excluded be.

Intervention groups
Group A (placebo): Patients who received a placebo treatment during the study. Group B (intervention): Patients who received probiotics during the study.

Main outcome variables
Determination of serum concentration of IL6, TNFa, IL10. Improvement in depression and mania symptoms based on Hamilton, Young Mania and Clinical global impression and improvement bipolar questionnaires.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180819040836N1**
Registration date: **2018-10-02, 1397/07/10**
Registration timing: **retrospective**

Last update: **2018-10-02, 1397/07/10**
Update count: **0**

Registration date
2018-10-02, 1397/07/10

Registrant information

Name
Mahdi Esmaeilzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-05-31, 1397/03/10

Expected recruitment end date
2018-06-20, 1397/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the Effect of Probiotics Augment in Treatment of Bipolar Disorder.

Public title
The Effect of Probiotics in Treatment of Bipolar Disorder.

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Detection of type 1 bipolar disorder based on DSM5. Age 18 to 65 years old. No change in dosage of antipsychotics, lithium and sodium valproate in the 2 weeks prior to entering the study and during treatment.
Exclusion criteria:
Pregnancy and Lactation. Hypersensivity to lactose. Chronic diseases (heart, kidney, lung and liver). Use of supplements and probiotics in the last 2 months. Schizophrenia and other psychotic disorders. seizure.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
This study is a simple, randomized clinical trial.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, patients are coded into two groups of 30, A (placebo) and B (probiotic). Placebo is a placebo. None of the participants in the study, the person who is analyzing the data, as well as the investigator, are unaware of these codes, so the double blind study.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Kerman University of Medical Sciences
Street address
Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran
City
Kerman
Province
Kerman
Postal code
7616913555
Approval date
2018-05-30, 1397/03/09
Ethics committee reference number
IR.KMU.AH.REC.1397.009

Health conditions studied

1

Description of health condition studied
Type 1 bipolar disorder
ICD-10 code
F31
ICD-10 code description
Bipolar disorder

Primary outcomes

1

Description
Determination of serum IL-6 concentration
Timepoint
Measurement of serum IL-6 concentration at baseline,1month and 2 months later
Method of measurement
A kit for measuring serum levels of IL-6

2

Description
Determination of serum IL-10 concentration
Timepoint
Measurement of serum IL-10 concentration at baseline, 1 month and 2 months later
Method of measurement
A kit for measuring serum levels of IL-10

3

Description
Determination of serum TNF-a concentration
Timepoint
Measurement of serum TNF-a concentration at baseline, 1 month and 2 months later
Method of measurement
A kit for measuring serum levels of TNF-a

Secondary outcomes

1

Description
Hamilton Scale of Depression Scale
Timepoint
At the start of the study, one month and two months later
Method of measurement

Based on the Hamilton Depression Questionnaire

2

Description
Scale Young Mania Scale
Timepoint
At the start of the study, one month and two months later
Method of measurement
Based on Young Mania Questionnaire

3

Description
Improvement of Mania Symptoms and Depression
Timepoint
At the start of the study, one month and two months later
Method of measurement
Based on the Clinical Global Impression and Impronement Bipolar Questionnaire

Intervention groups

1

Description
Intervention group: Patients with type 1 bipolar disorder who are treated with a probiotic capsule(Bioflora) for 2 months.
Category
Treatment - Drugs

2

Description
Control group: Patients with type 1 bipolar disorder who receive daily treatment with one capsule of placebo for 2 months.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital of Kerman
Full name of responsible person
Mahdi Esmaeilzadeh
Street address
Shahid Beheshti Hospital, 5th km of Jomhouri Blv.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Abbas pardakhty
Street address
Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran
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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
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Mahdi Esmaeilzadeh
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Psychiatrics
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Person responsible for scientific inquiries

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Name of organization / entity
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Person responsible for updating data

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Position
Resident
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Other areas of specialty/work
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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
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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
At the end of the study, part of the information included the serum levels of IL-6, 10, TNF-a and the Hamilton-Yang Mania Scale, and also the Clinical Global Impressiom and Improvement Bipolar, after identifying individuals, to the field enthusiasts Health is being shared.
When the data will become available and for how long
2 months after data analysis
To whom data/document is available
Researchers in the field of health
Under which criteria data/document could be used
In order to use the results and at the written request
From where data/document is obtainable
Mahdi esmaeilzadeh- Email
What processes are involved for a request to access data/document
The purpose of accessing data - Request to email
Comments