

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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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Email address

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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. Hypersensitivity 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, 1 month 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 Jomhuri 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

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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**Contact****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Mahin Eslami

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

Resident

Latest degree

Medical doctor

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 Impression 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