Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

Evaluation of the effect of probiotic supplements as adjunctive therapy in improving the symptoms of psychosis, anxiety, insomnia and anorexia due to amphetamine and methamphetamine use. A double-blind randomized placebo-controlled clinical trial at Imam Hossein Hospital

Protocol summary

Study aim
Evaluation of the effect of probiotic supplements as adjunctive therapy in improving the symptoms of psychosis, anxiety, insomnia and anorexia due to amphetamine and methamphetamine use

Design
A double-blind randomized placebo-controlled clinical trial at Imam Hossein Hospital with a parallel group design of 50 patients, enrolled between April 2022 , and followed for 8 weeks, simple random sampling.

Settings and conduct
A double-blind randomized placebo-controlled clinical trial at Imam Hossein Hospital with a parallel group design of 50 patients. Researcher and patients are blinded. Similar capsules of the drug-placebo are given randomly with codes one and two.

Participants/Inclusion and exclusion criteria
Inclusion criteria: positive amphetamine and methamphetamine test; diagnosis of amphetamine use disorder based on DSM5 criteria after interview; voluntary organization of the individual and his / her guardian to participate in the project; age: 18 to 60 years old old; IQ above 70; not receiving to receive electroshock in the last two weeks; do not use other drugs; lack of other psychiatric disorders. Exclusion criteria: prominent neurological or organic disease and cardiovascular disease and history of cardiac surgery or any cardiovascular procedure, clinical and laboratory examinations and family history; IQ less than 70 based on clinician clinical suspicion; abusing of other substances (except nicotine and caffeine); taking oral antipsychotics in the past week or long-acting antipsychotics in the past month; receiving ECT in the last two weeks; women of childbearing age will not be accepted without adequate methods of contraception; CHF and liver disease.

Intervention groups
intervention : lactobacillus acidophilus capsule 10 exponent 8 unit daily 8 weeks Control : Starch placebo tablets exactly the same with probiotic capsules 8 weeks

Main outcome variables
Amphetamine-induced psychosis; anxiety; insomnia and loss of appetite

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220205053945N1**
Registration date: **2022-03-17, 1400/12/26**
Registration timing: **prospective**

Last update: **2022-03-17, 1400/12/26**
Update count: **0**

Registration date
2022-03-17, 1400/12/26

Registrant information

Name
Maryam Rashidian

Name of organization / entity
Alborz University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 21 5564 8814

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-20, 1401/02/30
Expected recruitment end date
2022-06-10, 1401/03/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of probiotic supplements as adjunctive therapy in improving the symptoms of psychosis, anxiety, insomnia and anorexia due to amphetamine and methamphetamine use. A double-blind randomized placebo-controlled clinical trial at Imam Hossein Hospital

Public title
Evaluation of the effect of probiotic supplements as adjunctive therapy in improving the symptoms of psychosis, anxiety, insomnia and anorexia due to amphetamine and methamphetamine use
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Positive amphetamine and methamphetamine test Diagnosis of amphetamine use disorder based on DSM5 criteria after interview with psychiatrist Voluntary organization of the individual and his / her guardian to participate in the project Age: 18 to 60 years old IQ above 70 Not receiving to receive electroshock in the last two weeks Do not use other drugs (all opioids, morphine and methadone and marijuana are taken from the patient during the evaluation - testing of urinary toxic acid for amphetamine and methamphetamine) Lack of other psychiatric disorders such as schizophrenia Bipolar disorder Depression with psychosis
Exclusion criteria:
Prominent neurological or organic disease and cardiovascular disease and history of cardiac surgery or any cardiovascular procedure, clinical and laboratory examinations and review of family history and records Another diagnosis in Axis I based on DSM-V IQ less than 70 based on clinician clinical suspicion Abusing of other substances (except nicotine and caffeine) Taking oral antipsychotics in the past week or long-acting antipsychotics in the past month Receiving ECT in the last two weeks Women of childbearing age will not be accepted without adequate methods of contraception CHF and liver disease
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Initially, people with amphetamine and methamphetamine use disorders are identified based on a positive amphetamine and methamphetamine test and then a full interview by a psychiatrist with DSM5 characteristics. Persons that are included in the study are divided into two groups of intervention and control by simple randomization methods, in which agreed from the beginning that the intervention group will be given individual numbers and the control group will be given even numbers. Then, according to the number of study sample volumes, from the table of random numbers, relevant numbers are extracted. Each number is written on a card and placed in an envelope. The envelopes are sealed and the patient number is written on each envelope. Patient No. 1, Patient No. 2 will be given Envelope No. 2 and so on. In the same way, this work will continue until the end of the study sample volume. To maintain randomization, the person who prepares the envelopes is different from the person who registers the patients and provides the envelopes to the patients.
Blinding (investigator's opinion)
Double blinded
Blinding description
The study is double-blind and the researcher and the patient will not know the type of drug and the drugs are selected by another person in the form of capsules completely similar to the drug-placebo and the patient is given a completely random one between the drug and the placebo with code one and two.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Alborz University of Medical Sciences
Street address
Ethics Committee Office, 2nd floor, Deputy of Research and Technology, Saffarian Alley, 45 meters from Gol-shahr
City
Karaj
Province
Alborz

Postal code
3198764653
Approval date
2022-02-01, 1400/11/12
Ethics committee reference number
IR.ABZUMS.REC.1400.302

Health conditions studied

1

Description of health condition studied
substance induced psychosis
ICD-10 code
F19.251
ICD-10 code description
Other psychoactive substance dependence with psychoactive substance-induced psychotic disorder with hallucinations

Primary outcomes

1

Description
Amphetamine and methamphetamine-induced psychosis
Timepoint
At the beginning of this study, 4th and 8th weeks
Method of measurement
Brief Psychiatric Rating Scale

2

Description
The Beck Anxiety Inventory (BAI)
Timepoint
At the beginning of this study, 4th and 8th weeks
Method of measurement
The Beck Anxiety Inventory (BAI)

3

Description
Pittsburgh sleep quality index
Timepoint
At the beginning of this study, 4th and 8th weeks
Method of measurement
Pittsburgh Sleep Quality Index (PSQI)

Secondary outcomes

1

Description
Mild gastrointestinal discomfort
Timepoint
At the beginning of this study, 4th and 8th weeks
Method of measurement
Medical history

Intervention groups

1

Description
Intervention group: lactobacillus acidophilus capsule 10 exponent 8 unit daily for 8 weeks
Category
Treatment - Drugs

2

Description
Control group: Starch placebo tablets exactly the same with probiotic capsules for 8 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein hospital
Full name of responsible person
Atefe Zandifar
Street address
Mansour Nobakht St., Imam Khomeini Blvd., ,Mohammad Shahr ,Karaj
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Karaj
Province
Alborz
Postal code
31876 59348
Phone
+98 26 3419 3133
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+98 26 3419 3203
Email
emamhosein.hospital@abzums.ac.ir
Web page address
https://emamhossein.abzums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Alborz university of medical sciences
Full name of responsible person
Hatam Godini
Street address
Safarian St , Golshahr Ave, Karaj
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Postal code
3198764653

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+98 26 3464 3705
Email
Research@abzums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Alborz 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
Alborz university of medical sciences
Full name of responsible person
Atefe Zandifar
Position
Assistant professor of psychiatry,Alborz University of Medical Sciences
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
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Person responsible for updating data

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emamali@abzums.ac.ir

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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be 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
No - There is not a plan to make this available
Title and more details about the data/document

We are going to share required data

When the data will become available and for how long

available on March 2022

To whom data/document is available

Public article

Under which criteria data/document could be used

Unconditional

From where data/document is obtainable

Publisher journal or please sent massage to ah.hajialigol@gmail.com

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

sent massage to ah.hajialigol@gmail.com

Comments