

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Randomized controlled trial metabolic effects of adding Topiramate on Aripiprazole in bipolar patients under age 18

Protocol summary

Study aim

Metabolic effects of adding Topiramate on Aripiprazole in bipolar patients under age 18

Design

Double blinded randomized clinical trial, parallel group, randomized, phase 3 on 40 bipolar patients between age 6-18 years, randomization was done with computer randomization.

Settings and conduct

This trial will be conducted during 3 phases (0, 1, 3 month) in new bipolar patients between age 6-18 that be visited in outpatient units or admission wards of department of child psychiatry of Isfahan University of Medical Sciences. All of participants, health care providers (that are involved in offering drug or placebo to participants) and data collectors and assessors will be blinded with similarity in form and shape of drug and placebo and numerical codes for each participants instead of name in all time of study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: consent to participate in the study by completing the informed consent form by patient and family, Lack of any chronic physical illness, negative history of receiving any antipsychotic drug or mood stabilizers or drugs that could change appetite or weight during recent 3 month before study, lack of history of allergic reaction to topiramate and lack of history of renal insufficiency or renal stone. Exclusion criteria: patient or family unwillingness to stay in study, need to ECT treatment during study any unexpected new physical illness that could change medical care of patient.

Intervention groups

Intervention group will receive drug combination of Aripiprazole and Topiramate (drug A) and control group will receive Aripiprazole and placebo (drug B).

Main outcome variables

In the beginning of study and in end of month 1 and 3, metabolic indices of patients such as height, weight,

waist circumference, TG, BMI, Fasting insulin, Hb A1C, HDL, LDL, FBS, Cholesterol will be assessed as severity of bipolar disorder.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200606047668N1**

Registration date: **2020-06-20, 1399/03/31**

Registration timing: **prospective**

Last update: **2020-06-20, 1399/03/31**

Update count: **0**

Registration date

2020-06-20, 1399/03/31

Registrant information

Name

Mostafa Haghshenas

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 4572 2109

Email address

mhaghshenas@resident.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-21, 1399/02/02

Expected recruitment end date

2021-07-23, 1400/05/01

Actual recruitment start date

2020-06-21, 1399/04/01

Actual recruitment end date

2021-07-23, 1400/05/01
Trial completion date
 2021-10-23, 1400/08/01

Scientific title
 Randomized controlled trial metabolic effects of adding Topiramate on Aripiprazole in bipolar patients under age 18

Public title
 Metabolic effects of adding Topiramate on Aripiprazole in bipolar patients under age 18

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Consent to participate in the study by completing the informed consent form by patient and family. Lack of any chronic physical illness. Negative history of receiving any antipsychotic drug or mood stabilizers or drugs that could change appetite during recent 3 month before study Lack of history of allergic reaction to topiramate Lack of history of renal insufficiency or renal stone Age between 6-18 years
Exclusion criteria:
 patient or family unwillingness to stay in study Need to ECT treatment during study Any unexpected new physical illness that could change medical care of patient

Age
 From **6 years** old to **18 years** old

Gender
 Both

Phase
 3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
 Target sample size: **38**
 Actual sample size reached: **40**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Online randomization with random assignment by blocks approach will be done by online RESEARCH RANDOMIZER software and then each number on each group of study will receive a new code so allocation concealment will be carried out.

Blinding (investigator's opinion)
 Double blinded

Blinding description
 Participants in both intervention and control group will be blinded about drug or placebo with similarity in shape of drug and placebo. principle investigator will be blinded with random placing the participants in both control and intervention group so give each participant a numerical code. health care providers offer the drug and placebo base on A and B codes to participants and data collectors and outcome assessors will be blinded

because they will collect data and assess them without any information about drug or placebo type.

Placebo
 Used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences

Street address

Hezar Jerib street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2020-06-19, 1399/03/30

Ethics committee reference number

IR.MUI.MED.REC.1399.235

Health conditions studied

1

Description of health condition studied

Bipolar disorder

ICD-10 code

F31

ICD-10 code description

Bipolar affective disorder

2

Description of health condition studied

Metabolic syndrome

ICD-10 code

E90

ICD-10 code description

Nutritional and metabolic disorders in diseases classified elsewhere

Primary outcomes

1

Description

Bipolar disorder

Timepoint

Before intervention and 1,3 months after intervention

Method of measurement

2

Description

Fasting blood glucose

Timepoint

Before intervention and 1,3 months after intervention

Method of measurement

Lab kit

3

Description

Triglyceride

Timepoint

Before intervention and 1,3 months after intervention

Method of measurement

Lab kit

4

Description

Glycated hemoglobin

Timepoint

Before intervention and 1,3 months after intervention

Method of measurement

Lab kit

5

Description

Cholestrol

Timepoint

Before intervention and 1,3 months after intervention

Method of measurement

Lab kit

6

Description

Low density lipoprotein

Timepoint

Before intervention and 1,3 months after intervention

Method of measurement

Lab kit

7

Description

High density lipoprotein

Timepoint

Before intervention and 1,3 months after intervention

Method of measurement

Lab kit

8

Description

Fasting insulin

Timepoint

Before intervention and 1,3 months after intervention

Method of measurement

Lab kit

9

Description

Blood pressure

Timepoint

Before intervention and 1,3 months after intervention

Method of measurement

sphygmomonometer

10

Description

Waist circumference

Timepoint

Before intervention and 1,3 months after intervention

Method of measurement

Standard meter

11

Description

Weight

Timepoint

Before intervention and 1,3 months after intervention

Method of measurement

Standard scale

12

Description

Height

Timepoint

Before intervention and 1,3 months after intervention

Method of measurement

Standard meter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Topiramate tablet (TOPIRAMATE-ARYA 25MG TAB) with dose 25-100mg daily, once daily orally for 3 months

Category

Treatment - Drugs

2

Description

Control group: placebo tablet(School of Pharmacy and Pharmaceutical SciencesSchool of Isfahan University of Medical Sciences) contains starch and calcium diphosphate with dose 1-4 tablet per day orally and once daily.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Amin hospital

Full name of responsible person

Dr Hamid Melali

Street address

Ebn e Sina street

City

Isfahan

Province

Isfahan

Postal code

8148653141

Phone

+98 31 1445 5051

Email

Amin@mui.ac.ir

2

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Dr Majid Rezvani

Street address

Soffeh blvd

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 1668 5555

Email

Alzahra@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr Shaghayegh Haghjoo Javanmard

Street address

Hezar jerib street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 8138

Email

sh_haghjoo@med.mui.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Mostafa Haghshenas

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Hezar jerib street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 4572 2109

Email

Tamasha_jums@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mostafa Haghshenas

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Hezar Jerib street

City
Isfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 4572 2109
Email
Tamasha_jums@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mostafa Haghshenas
Position
Resident
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
Hezar Jerib street
City
Isfahan
Province
Isfahan

Postal code
8344179134
Phone
+98 31 4572 2109
Email
Tamasha_jums@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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available