Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 bipoar patients under age 18

Design

Double blinded randomized clinical trial,parallel group, randomized, phase3 on 40 bipolar patients betwren 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 recieving any antypsychotic 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 recieve drug combination of Aripiprazole and Topiramate(drug A)and control group will recieve Aripiprazole and placebo(drug B).

Main outcome variables

In the begining 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)

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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 recieving any antypsychotic 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 aproach will be done by online RESEARCH RANDOMIZER software and then each number on each group of study will recive a new code so allocation concealment will be carried out.

Blinding (investigator's opinion)

Double blinded

Blinding description

Paricipants 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 randomal placing the participants in both control and intervention group so give each paticipant a numerical code.health care providers offer the drug and placebo base on A and B codes to participants and data callectors 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

Isfehan

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

Young mania rating scale

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
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2

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

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Name of organization / entity
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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
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
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Mostafa Haghshenas
Position
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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