Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Topiramate’s effectiveness on weight reduction and metabolic syndrome in obese patients with schizophrenia and schizoaffective

Protocol summary

Study aim

To assess the effect of topiramate on weight change and metabolic syndrome in obese patients with schizophrenia and schizoaffective disorder

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 66 patients. Random allocation software was used for randomization.

Settings and conduct

This study is an experimental study of double-blind controlled clinical trial (RCT) using placebo in all patients with schizophrenia and schizoaffective hospitalization in men and women wards of Razi Psychiatric Hospital. Individuals are selected based on inclusion criteria and then randomly divided into intervention and control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 65 years BMI above 27 schizophrenia or schizoaffective disorder Obtaining informed consent from the patient and the patient's legal guardian Inclusion criteria: Diabetes Pregnancy or breastfeeding Unmodified thyroid disease Patients with heart failure Patients with kidney problems Hypersensitivity to topiramate Patient reluctance Use of iodinated contrast agents during the last 1 month Alcohol and drug addiction

Intervention groups

Participants will be randomly (in alphabetical order) divided into two groups of men and women, and each of these groups will be divided into intervention and control groups. Topiramate 50 mg tablets of Aria Pharmaceutical Company and placebo in the form of uniformly packed tablets And will be presented to patients with the names of A and B by the center nurse.

Main outcome variables

It is expected that the following variables change in the Intervention group after the intervention. Patients' weight BMI Abdomen circumference Fasting blood cholesterol level HDL (High Density Cholesterol) LDL (Low Density Cholesterol) -TG (triglyceride) -FBS

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210622051665N1**
Registration date: **2021-07-25, 1400/05/03**
Registration timing: **retrospective**

Last update: **2021-07-25, 1400/05/03**
Update count: **0**

Registration date

2021-07-25, 1400/05/03

Registrant information

Name

Hamidreza Kamravan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6683 4793

Email address

kamravan@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-09-10, 1399/06/20

Actual recruitment start date

2020-02-21, 1398/12/02

Actual recruitment end date

2020-09-23, 1399/07/02

Trial completion date

2020-09-23, 1399/07/02

Scientific title
Topiramate’s effectiveness on weight reduction and metabolic syndrome in obese patients with schizophrenia and schizoaffective

Public title
Topiramate’s effectiveness on weight reduction and metabolic syndrome in obese patients with schizophrenia and schizoaffective

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 18 to 65 years BMI above 27 Patients with schizophrenia or schizoaffective disorder receiving a second-generation antipsychotic drug Obtaining informed consent from the patient and the patient's legal guardian

Exclusion criteria:
Diabetis Pregnancy or breastfeeding Patients with heart failure Patients with kidney disease Hypersensitivity to topiramate

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **70**
Actual sample size reached: **66**

Randomization (investigator's opinion)
Randomized

Randomization description
The collected samples were randomly divided into two groups based on the random sequence created in the Random allocation software to the drug and placebo.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, sampling is performed by the researcher and the interventions are performed by the nurse. Also, the sampler does not know that the sample is part of the control or intervention group.The patients in this study are also unaware of being in the intervention or control group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Social Welfare and Rehabilitation Sciences University of Medical Sciences

Street address
kodakyar Ave., daneshjo Blvd.,Evin

City
Tehran

Province
Tehran

Postal code
1985713871

Approval date
2020-01-15, 1398/10/25

Ethics committee reference number
IR.USWR.REC.1399.250

Health conditions studied

1

Description of health condition studied
Schizophrenia,Schizoaffective

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
BMI>27

Timepoint
before study and in weeks 4,8 and 12

Method of measurement
measure height and weight

2

Description
measure abdominal circumference

Timepoint
before study and in weeks 4,8 and 12

Method of measurement
Tape meter

3

Description
FBS

Timepoint
before the study and in weeks 4,8 and 12

Method of measurement
Blood sample and lab result

4

Description

Total cholesterol

Timepoint

before the study and in weeks 4,8 and 12

Method of measurement

Blood sample and lab result

5

Description

Triglyceride

Timepoint

before the study and in weeks 4,8 and 12

Method of measurement

Blood sample and lab result

Secondary outcomes

empty

Intervention groups

1

Description

Patients were randomly divided (in alphabetical order) into two groups of men and women, and each of these groups was divided into intervention and control groups. A total of 33 patients entered the intervention group. In order to observe the ethical issues of diet and the amount of appropriate daily activity, the condition of all patients was observed based on consultation with a nutritionist and similar conditions were established in the two groups of topiramate and control. Topiramate 50 mg tablets of Aria Pharmaceutical Company were packaged in the same shape as tablets and presented to the patients by the center nurse. Initially one capsule daily in the morning and after one week, two daily capsules (one capsule in the morning and one capsule in the evening) will be given until the end of week 12.

Category

Treatment - Drugs

2

Description

Control group: Patients were randomly divided (in alphabetical order) into two groups of men and women, and each of these groups was divided into intervention and control groups. A total of 33 patients entered the intervention group. In order to observe the ethical issues of diet and the amount of appropriate daily activity, the condition of all patients was observed based on consultation with a nutritionist and similar conditions were established in the two groups of topiramate and control. The placebo pill was packaged in the same shape as the tablets and presented to the patients by the center nurse. Initially one capsule daily in the morning and after one week, two daily capsules (one capsule in the morning and one capsule in the evening) will be given until the end of week 12.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Psychiatric Hospital

Full name of responsible person

Hamidreza Kamravan

Street address

Shahr Rey, Shahid Rastegar Boulevard

City

Tehran

Province

Tehran

Postal code

1866958891

Phone

+98 21 3340 1222

Email

kamravan@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Hamidreza Kamravan

Street address

Tehran, Shahreri, Shahid Rastegar Boulevard

City

Tehran

Province

Tehran

Postal code

1345935775

Phone

+98 21 6683 4793

Email

kamravan@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

University of social welfare and rehabilitation 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
University of social welfare and rehabilitation sciences

Full name of responsible person
Hamidreza Kamravan

Position
psychiatric resident

Latest degree
Medical doctor

Other areas of specialty/work
Psychiatrics

Street address
Tehran, Shahreri, Shahid Rastegar Boulevard

City
Tehran

Province
Tehran

Postal code
1345935775

Phone
+98 21 6683 4793

Email
kamravan@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
University of social welfare and rehabilitation sciences

Full name of responsible person
Hamidreza Kamravan

Position
Psychiatry resident

Latest degree
Medical doctor

Other areas of specialty/work
Psychiatrics

Street address
Azarbayejan, Foad moosavi street, bani asadi Avenue, No 7.

City
Tehran

Province
Tehran

Postal code
1345935775

Phone
+98 21 6683 4793

Fax

Email
kamravan@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
University of social welfare and rehabilitation sciences

Full name of responsible person
Hamidreza Kamravan

Position
Psychiatry resident

Latest degree
Medical doctor

Other areas of specialty/work
Psychiatrics

Street address
Azarbayejan, Foad moosavi street, bani asadi Avenue, No 7.

City
Tehran

Province
Tehran

Postal code
1345935775

Phone
+98 21 6683 4793

Fax

Email
kamravan@gmail.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
No - There is not 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