

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Effect of Topiramate on body weight of patients with schizophrenia treated with Olanzapine in Ibn-e- Sina Hospital in 2006.

Protocol summary

Summary

Aim of this study is effect of Topiramate on body weight of patients with schizophrenia treated with Olanzapine in Ibn-e- Sina Hospital in 2006. This study is double-blind clinical trial. 48 schizophrenic patients treated with Olanzapin which have including criteria for study at the beginning of hospitalization in Ibn-e- Sina Hospital are introduce into 4 groups randomly. Placebo, 50,100, 200 mg Topiramate is adding to their daily treatment. The inclusion criteria included: Schizophrenia according to DSM-IV-IR; aged between 18-60 years. Exclusion criteria included: Substance abuse in the past six months, a history of seizures, concomitant use of other drugs except benzodiazepines and beta-blockers. Then, patients are follow-up for 12 weeks for body weight changes, BMI, waist and wrist.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201402085280N15**
Registration date: **2014-03-10, 1392/12/19**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-03-10, 1392/12/19

Registrant information

Name

Raheleh Nejati

Name of organization / entity

Mashhad University of Medical Scinces, Ibn-e- Sina
Psychiatric Hospital

Country

Iran (Islamic Republic of)

Phone

+98 51 3711 2540

Email address

nejatir2@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2008-11-22, 1387/09/02

Expected recruitment end date

2009-08-24, 1388/06/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Topiramate on body weight of patients with schizophrenia treated with Olanzapine in Ibn-e- Sina Hospital in 2006.

Public title

Effect of Topiramate on body weight of patients with schizophrenia treated with Olanzapine

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criteria included: Schizophrenia according to DSM-IV-IR; aged between 18-60 years. Exclusion criteria included: Substance abuse in the past six months, a history of seizures, concomitant use of other drugs except benzodiazepines and beta-blockers .

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 48

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

Street address

Ghoreish building, Daneshgah Street.

City

Mashhad

Postal code

Approval date

2006-11-09, 1385/08/18

Ethics committee reference number

85158

Health conditions studied

1

Description of health condition studied

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

weight

Timepoint

0,1,2,4,6,8,12 weeks

Method of measurement

Balance

2

Description

Around the wrist

Timepoint

0,4,8,12 weeks

Method of measurement

Meter

3

Description

Waist

Timepoint

0,4,8,12 weeks

Method of measurement

meter

Secondary outcomes

1

Description

Clinical tests (FBS,UREA, TG, SGOT,SGPT,Cholestrol)

Timepoint

Baseline and end of plan

Method of measurement

in Laboratory

Intervention groups

1

Description

in intervention group 50 mg topiramate added to their daily treatment in 12 week.

Category

Treatment - Drugs

2

Description

in intervention group 100 mg topiramate added to their daily treatment in 12 week

Category

Treatment - Drugs

3

Description

in intervention group 200 mg topiramate added to their daily treatment in 12 week

Category

Treatment - Drugs

4

Description

in control group placebo added to their daily treatment in 12 week.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ibn-e- Sina Hospital

Full name of responsible person

Street address

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Ardakanian Marjan

Street address

Ghoreish building, Daneshgah street.

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohammad Reza Fayyazi Bordbar

Position

Associate Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Mashhad University of Medical Sciences

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Dr Ali Talaei

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Person responsible for updating data

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Mashhad University of Medical Sciences

Full name of responsible person

Raheleh Nejati

Position

Other areas of specialty/work

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Fax

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty