

# 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**

**Street address**

Ibn-e-Sina Hospital, Hore Ameli blv.

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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**

Dr Ali Talaei

**Position**

Associate Professor

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Raheleh Nejati

**Position**

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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*