

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Zonisamide for prevention of Atypical (Second generation) antipsychotics associated weight gain in schizophrenia : A double- blind, placebo controlled trial

#### Protocol summary

##### Summary

This is a double- blind, randomized placebo controlled trial to investigate the possible effect of zonisamide on prevention of weight gain in patients with schizophrenia taking atypical antipsychotics. The participants are 56 patients that they will be allocated to one of the two parallel groups. One group takes zonisamide (up to 150 mg/day) plus antipsychotics. The other group will receive antipsychotic plus placebo. Duration of this study is 10 weeks. Assessment includes evaluation of height, weight, and waist circumference. The patients will be assessed at pre-intervention, week 4, week 8, and week 10 after intervention onset. Patients with schizophrenia administered atypical antipsychotics are included. Those with a marked medical condition will be excluded.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201103283930N5**

Registration date: **2011-07-13, 1390/04/22**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2011-07-13, 1390/04/22

##### Registrant information

###### Name

Ahmad Ghanizadeh

###### Name of organization / entity

Research Center for Psychiatry and Behavioral Sciences, Shiraz University Of Medical Sciences

###### Country

Iran (Islamic Republic of)

##### Phone

+98 71 1627 3070

##### Email address

ghanizad@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

##### Expected recruitment start date

2011-03-28, 1390/01/08

##### Expected recruitment end date

2012-03-27, 1391/01/08

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Zonisamide for prevention of Atypical (Second generation) antipsychotics associated weight gain in schizophrenia : A double- blind, placebo controlled trial

##### Public title

Zonisamide for prevention of Atypical (Second generation) antipsychotics associated weight gain in schizophrenia

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria are: age range of 16 to 65; lack of any reported neurological disease; lack of reported thyroid function problem; lack of current active substance use; lack of taking medication leading to significant weight gain or loss; no taking sulfanomides; lack of self reported kidney stone. Exclusion criteria are: lack of providing

written consent; any serious medical condition such as epilepsy, thyroid function problems, diabetes; breast feeding; pregnancy; any special nutritional regime or intensive exercise program to decrease weight.

#### Age

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

#### Gender

Both

#### Phase

2

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **56**

#### 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

Ethics committee of Shiraz University of Medical Sciences

##### Street address

Vice-chancellery for Research, Shiraz University of Medical sciences, Zand Street

##### City

Shiraz

##### Postal code

#### Approval date

2011-03-15, 1389/12/24

#### Ethics committee reference number

Ct-89-5460

## Health conditions studied

### 1

#### Description of health condition studied

schizophrenia

#### ICD-10 code

F20

#### ICD-10 code description

Schizophrenia

## Primary outcomes

### 1

#### Description

height

#### Timepoint

preintervention, weeks of 4, 8, and 10

#### Method of measurement

centimeter

### 2

#### Description

Weight

#### Timepoint

preintervention, weeks of 4, 8, and 10

#### Method of measurement

kilogram

### 3

#### Description

waist circumference

#### Timepoint

preintervention, weeks of 4, 8, and 10

#### Method of measurement

Centimeter

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Zonisamide (150mg/day), Single dosage

#### Category

Treatment - Drugs

### 2

#### Description

Placeb

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Research Center for Psychiatry and Behavioral Sciences, Shiraz University of Medical Sciences

##### Full name of responsible person

##### Street address

##### City

Shiraz

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for research, Shiraz University of  
Medical Sciences

**Full name of responsible person**

Gholam Reza Hatam

**Street address**

Zand Street, Shiraz University of Medical sciences-  
Vice-chancellery for Research

**City**

Shiraz

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

Yes

**Title of funding source**

Vice chancellor for research, Shiraz 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**

### Person responsible for scientific

## inquiries

**Contact****Name of organization / entity**

Shiraz University of Medical sciences

**Full name of responsible person**

Ahmad Ghanizadeh

**Position**

MD

**Other areas of specialty/work****Street address**

Chamran street, Hafez Hospital

**City**

Shiraz

**Postal code****Phone**

+98 71 1627 3070

**Fax****Email**

ghanizad@sina.tums.ac.ir

**Web page address**

### Person responsible for updating data

**Contact**

### 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*