

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of incidence of metabolic abnormalities in schizophrenic patients treating with olanzapine and sitagliptin in comparison with olanzapine and placebo

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Evaluation of the incidence of metabolic abnormalities in schizophrenic patients treating with olanzapine and sitagliptine in comparison with olanzapine and placebo

Last update: **2020-01-07, 1398/10/17**

Update count: **0**

Registration date

2020-01-07, 1398/10/17

Design

Two arm parallel group randomised trial double blinded ,with outcome assessment

Registrant information

Name

Elahe Memari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3834 8098

Email address

elahe.memari@yahoo.com

Settings and conduct

Hospitalized schizophrenic patients in Ebnesina Hospital affiliated to Shiraz Medical Sciences University, are divided randomly to two groups and followed for 12 weeks. Body mass index, waist circumference, blood lipids, blood sugar and blood pressure are measured at beginning, week 4 and week 12.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Hospitalized schizophrenic patients who are 18-65 years old, and treating with olanzapine. They do not have other psychiatric disorder and major medical problems. They do not use substances and they are not pregnant

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-06-20, 1399/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Intervention groups

The placebo group and sitagliptin group receive placebo and sitagliptin for 12 weeks. Physical examination and measurement of vital signs, anthropometric characteristics and laboratory parameters are done at beginning, week 4 and week 12 of study

Main outcome variables

Effect of sitagliptin on body mass index, waist circumference, blood lipids, blood sugar and blood pressure

Scientific title

Evaluation of incidence of metabolic abnormalities in schizophrenic patients treating with olanzapine and sitagliptin in comparison with olanzapine and placebo

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191210045677N1**

Registration date: **2020-01-07, 1398/10/17**

Public title

Effect of sitagliptin on metabolic abnormalities in

schizophrenic patients treating with olanzapine

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Diagnosis of schizophrenia based on DSM-5 criteria and clinical interview treating with olanzapine
Exclusion criteria:
 Diagnosis of other mental disorders Major medical problems(cardiovascular,pulmonary,gastrointestinal,renal) Substance use Pregnancy Premorbid or comorbid metabolic abnormalities(obesity,diabetes,hypertension,hyperlipidemia)

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization with random number table.In this method, individuals are numbered from 1 to n (number of sample) without sequencing to have an equal chance each individual.Then, in the random number table provided by the computer, a number is randomly selected as the source of the sample and, given the position of the number in the table (rows and columns), rows of n numbers are considered.The numbers in the selected rows are read in order n The number corresponding to the community numbering indicates the row number of people to be selected in the sample.A proportional number is a number that is between 1 and n. Each repeated number is counted only once and the numbers outside the range n are deleted. Drugs are numbered in similar envelopes depending on the order of assignment, and it is important to note that the envelopes are opened periodically and after the participant's name is inserted.Patients are assigned to a target group by a person other than the researcher (for example, the head of the inpatient ward), and the list is kept.

Blinding (investigator's opinion)
Double blinded

Blinding description
The tablets have the same shape and color.They are distributed randomly among the patients.The researcher,patients,data analyzer and data safety and monitoring committee are not aware of each patient s medication

Placebo

Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics in research committee of Shiraz medical school
Street address
 No.75, Alley 62/5,Pasdaran Blvd
City
 Shiraz
Province
 Fars
Postal code
 7184977879
Approval date
 2018-07-29, 1397/05/07
Ethics committee reference number
 IR.SUMS.MED.REC.1397.187

Health conditions studied

1

Description of health condition studied
 Metabolic abnormalities in schizophrenic patients treating with olanzapine

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
 blood sugar

Timepoint
 At beginning,week 4 and week 12 of study

Method of measurement
 Measurement of fasting blood sugar via laboratory tests

2

Description
 weight

Timepoint
 At beginning,week 4 and week 12 of study

Method of measurement
 weight measurement with balance

3

Description

lipid profile

Timepoint

At beginning, week 4 and week 12 of study

Method of measurement

Measurement of fasting blood lipids via laboratory tests

4

Description

Waist circumference

Timepoint

At beginning, week 4 and week 12 of study

Method of measurement

Measurement by meter

5

Description

Blood pressure

Timepoint

At beginning, week 4 and week 12 of study

Method of measurement

Measurement of blood pressure by Mercury barometer

Secondary outcomes

1

Description**Timepoint****Method of measurement**

Intervention groups

1

Description

Intervention group: Prescription of 100 mg tablets of Sitagliptin manufactured by Dr. Abidi Pharmaceutical Company with daily use of 1 tablet for 12 weeks and measurement of body mass index, waist circumference, blood pressure, fasting blood sugar and lipid profile at beginning, week 4 and week 12 of study

Category

Treatment - Drugs

2

Description

Control group: Prescription of placebo tablets made by the Faculty of Pharmacy, Shiraz University of Medical Sciences, one tab daily for 12 weeks. Body mass index, waist circumference, blood pressure, fasting blood glucose, and fasting lipid profile are measured at baseline, after 4 weeks, and after 12 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Ebnesina hospital affiliated to Shiraz University of Medical Sciences

Full name of responsible person

Elahe Memari

Street address

Next to 13 Aban Garden, Hafez Avenue

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3228 9600

Email

sinahosp@sums.ac.ir

Web page address

<https://ebnesina.sums.ac.ir>

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Yoones Ghasemi PHD

Street address

7th floor, Central building of Shiraz University of Medical Sciences, Karim Khan Zand Street

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3235 7282

Fax

+98 71 3212 2430

Email

vcrdep@sums.ac.ir

Web page address

<http://research.sums.ac.ir>

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

Yes

Title of funding source

Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Elahe Memari

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

No 75, Alley 62/5, Pasdaran Blvd

City

Shiraz

Province

Fars

Postal code

7184977879

Phone

+98 71 3822 4845

Email

elahe.memari@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Ebrahim Moghimi Sarani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Ebnesina Hospital, Next to 13 Aban Garden, Hafez Avenue

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3228 9600

Email

moghimie@sums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Elahe Memari

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

No 75, Alley 62/5, Pasdaran Blvd

City

Shiraz

Province

Fars

Postal code

7184977879

Phone

+98 71 3822 4845

Email

elahe.memari@yahoo.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Participant data file (excluding address surname and telephone number), study protocol, statistical analysis, and clinical reports

When the data will become available and for how long

6 months after publication of the extract

To whom data/document is available

Academic researchers and affiliates with accredited research centers

Under which criteria data/document could be used

By carefully citing sources based on citation rules

From where data/document is obtainable

Sending Email to elahe.memari@yahoo.com

What processes are involved for a request to access data/document

Send email that includes precise personal information and purpose of data usage, review of request by academic, financier and researcher for approximately one month, submission of data file upon request approval

Comments