

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### An assessment of effects of melatonin on metabolic effects of olanzapine in patients with schizophrenia

#### Protocol summary

##### Summary

The purpose of this study is to assess the efficacy of melatonin in prevention of olanzapine-induced metabolic side effect in patients with schizophrenia. Forty patients with schizophrenia based on DSM-IV-TR criteria who are not pregnant or lactating and have no significant medical illness will be randomly assigned to treatment for 12 weeks with olanzapine, 15- 25 mg/day, plus melatonin, 3mgs(N=20), or olanzapine, 15-25 mg/day, plus placebo (N=20). This investigation will be conducted in a double-blind fashion. Planned assessments included blood pressure, body weight, body mass index, waist circumference, waist-to-hip ratio, fasting glucose and insulin, insulin resistance index at baseline, week 4, 8 & 12, and fasting lipids.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201107187049N1**

Registration date: **2011-09-10, 1390/06/19**

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

Last update:

Update count: **0**

##### Registration date

2011-09-10, 1390/06/19

##### Registrant information

###### Name

Mohamadjafar Modabernia

###### Name of organization / entity

Guilan University of Medical Sciences, Shafa hospital

###### Country

Iran (Islamic Republic of)

###### Phone

+98 13 1666 2360

##### Email address

gmodaber@gums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Guilan University of Medical sciences

##### Expected recruitment start date

2011-08-06, 1390/05/15

##### Expected recruitment end date

2012-05-04, 1391/02/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

An assessment of effects of melatonin on metabolic effects of olanzapine in patients with schizophrenia

##### Public title

An assessment of effects of melatonin on metabolic effects of olanzapine in patients with schizophrenia

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion Criteria: age 18-65 year; diagnosis of schizophrenia based on DSM-IV-TR; capability to take drugs at 9.00 pm Exclusion criteria: married women who are at reproductive age; history of drug abuse or dependence in the recent 30 days; history of taking olanzapine in the recent 3 months; history of allergy or intolerance to olanzapine; history of significant head trauma (causing loss of consciousness more than 5 minutes or neurological or cognitive sequelae); liver, kidney, cerebrovascular or cardiovascular disease; diabetes; metabolic syndrome; cancer; using antiepileptic, antihypertensive or anticoagulant or antiplatelet drugs; using inhibitors or stimulants of hepatic

isoenzymes that metabolize melatonin or olanzapine (e.g. omeprazole, rifampin, fluvoxamine, ciprofloxacin, carbamazepine, and modafinil); patients develop diabetes; acidosis; severe anticholinergic side effects; delirium or need for administration of another drug

**Age**

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

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

**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**

Guilan University of Medical sciences

**Street address**

Namjoo street, Rasht

**City**

Rasht

**Postal code**

41446-65385

**Approval date**

2011-07-05, 1390/04/14

**Ethics committee reference number**

190015211

**Health conditions studied****1****Description of health condition studied**

schizophrenia

**ICD-10 code**

F20-f29

**ICD-10 code description**

Schizophrenia, schizotypal and delusional disorders

**Primary outcomes****1****Description**

TRIGLYCERIDE

**Timepoint**

baseline, week 4, 8, 12

**Method of measurement**

Enzymatic procedure

**2****Description**

waist circumference

**Timepoint**

baseline, week 4, 8, 12

**Method of measurement**

with a plastic meter

**3****Description**

body mass index

**Timepoint**

baseline, week 4, 8, 12

**Method of measurement**

calculated as body weight(kg)divided by the height in meters square

**4****Description**

waist to hip ratio

**Timepoint**

baseline, week 4, 8, 12

**Method of measurement**

with a plastic meter

**5****Description**

LDL

**Timepoint**

baseline, week 4, 8, 12

**Method of measurement**

Enzymatic procedure

**6****Description**

HDL

**Timepoint**

baseline, week 4, 8, 12

**Method of measurement**

Enzymatic Procedure

**7****Description**

FBS

**Timepoint**

baseline, week 4, 8, 12

## Method of measurement

Enzymatic Procedure

## 8

### Description

Insulin resistance index

### Timepoint

baseline and at the end of intervention

### Method of measurement

with HOMA formula

## 9

### Description

Fasting serum Insulin values

### Timepoint

baseline and at the end of intervention

### Method of measurement

ELISA

## 10

### Description

Blood pressure

### Timepoint

baseline, week 4, 8, 12

### Method of measurement

mercury sphygmomanometer

## Secondary outcomes

## 1

### Description

improvement of sleep problems

### Timepoint

base, week 4, 8, 12

### Method of measurement

pittsburgh quality of sleep

## 2

### Description

severity of psychosis

### Timepoint

baseline, week 4, 8, 12

### Method of measurement

scale measurement by PANSS

## Intervention groups

## 1

### Description

tablet melatonin 3mg at 9 pm as intervention group

### Category

Placebo

## 2

### Description

placebo at 9 pm as control group

## Category

Placebo

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Shafa hospital. Guilan University of Medical Sciences

#### Full name of responsible person

Amirhossein Modabbernia

#### Street address

Shafa hospital, Toshiba square, Rasht

#### City

Rasht

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Guilan University of Medical Sciences

#### Full name of responsible person

Dr Abdolrasul Sobhani

#### Street address

Namjoo street

#### City

Rasht

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Guilan 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

Guilan University of Medical Sciences

#### Full name of responsible person

Dr. Mohamadjafar Modabbernia

#### Position

Psychiatrist

#### Other areas of specialty/work

#### Street address

Shafa hospital, Toshiba square, Rasht

#### City

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**Postal code**

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Guilan University of Medical Sciences

**Full name of responsible person**

Dr.Mohamad Jafar Modabbernia

**Position**

Psychiatrist

**Other areas of specialty/work**

**Street address**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Guilan University of Medical Sciences

**Full name of responsible person**

Dr.Parvaneh Heidari Rad

**Position**

Psychiatry resident

**Other areas of specialty/work**

**Street address**

Shafa hospital, Toshiba square,Rasht

**City**

Rasht

**Postal code**

**Phone**

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**Email**

**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*