

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

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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

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Full name of responsible person

Dr.Parvaneh Heidari Rad

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Other areas of specialty/work

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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