Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Melatonin attenuates antipsychotic metabolic effects:

Protocol summary

Summary

This study is a double blind controlled clinical trial to evaluate the effect of melatonin in reducing metabolic effects of second-generation antipsychotic drugs on patients 18 to 64 years old who has just been nominated for a second-generation antipsychotic medications. Patients with high blood pressure, diabetes, lipid disorders, thyroid disorders, and liver disease and patients who at any time during the study antipsychotic drugs abandoned or Do not take two doses of melatonin pill, are excluded. The study included 100 patients in each group of 50 people, and in the absence of exit criteria are enrolled for 8 weeks. a group of patients were administrated melatonin at a dose of 3 mg and placebo given to the control group, and the first and fourth week and eighth week of the study, changes in blood lipid profiles, blood sugar and blood pressure, waist circumference and body mass index are considered . l

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016051027832N1**
Registration date: **2016-09-27, 1395/07/06**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-09-27, 1395/07/06

Registrant information

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Mansour Agahi
Name of organization / entity
Kashan University of Medical Scienses
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2015-04-03, 1394/01/14

Expected recruitment end date

2016-08-31, 1395/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Melatonin attenuates antipsychotic metabolic effects:

Public title

Effect of Melatonin in side effects of second-generation antipsychotic medications

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: men and women 18 to 64 years old who have recently been treated with second-generation antipsychotics; Exclusion criteria: patients with high blood pressure, diabetes, lipid disorders, thyroid disorders and liver diseases; a history of sensitivity to melatonin; high risk of suicide or aggression; pregnant women or lactating; patients at any time during the study drugs antipsychotic abandoned or Do not take two doses of melatonin pill; substance Abuse or dependence in the last 6 months;

Age

From **18 years** old to **64 years** old

Gender

Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **100**
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
Kashan University Of Medical Sciences
Street address
5th Km, Ravand Blv, Kashan
City
Kashan
Postal code
Approval date
2015-01-28, 1393/11/08
Ethics committee reference number
93184

Health conditions studied

1

Description of health condition studied
schizophrenia
ICD-10 code
F20
ICD-10 code description
Schizophrenia

2

Description of health condition studied
bipolar disorder
ICD-10 code
F31
ICD-10 code description
Bipolar affective disorder

Primary outcomes

1

Description
blood pressure
Timepoint
before intervention and the end of 4th week & 8th week
Method of measurement
mmhg

2

Description
HDL
Timepoint
before intervention and the end of 4th week & 8th week
Method of measurement
mg/dl

3

Description
FBS
Timepoint
before intervention and the end of 4th week & 8th week
Method of measurement
mg/dl

4

Description
cholesterol
Timepoint
before intervention and the end of 4th week & 8th week
Method of measurement
mg/dl

5

Description
BMI
Timepoint
before intervention and the end of 4th week & 8th week
Method of measurement
kg/m2

6

Description
waist
Timepoint
before intervention and the end of 4th week & 8th week
Method of measurement
cm

Secondary outcomes

1

Description
side effects of melatonin
Timepoint
the end of 4th week & 8th week
Method of measurement

clinical interview and physical examination

Intervention groups

1

Description
control: Tab Placebo Hs oral for 8 weeks
Category
Prevention

2

Description
intervention: melatonin tablet 3 mg oral HS for 8 weeks
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Karegarnejad Hospital
Full name of responsible person
Mansour Agahi
Street address
5th km, Ravand Blv, Kashan
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Kashan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Gholam Ali Hamidi MD
Street address
5th Km, Ravand Blv, Kashan
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Kashan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kashan 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
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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