Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of Melatonin on the components of metabolic syndrome in adolescent bipolarpatients taking risperidone plus lithium carbonate: a randomized,double blind, placebo-controlled clinical trial

Protocol summary

Summary

The objective of this study is to assess the efficacy of melatonin in preventing the development of the components of metabolic syndrome in bipolar patients taking risperidone plus lithium.Design:a 12 weeks double-blind, randomized , placebo-controlled trial. 40 adolescents aged 11 to 17 years with Bipolar disorder will receive Risperidone (plus lithium combined with either placebo (N=20) or 3 mg/day of melatonin(N=20) for 12 weeks. Parameters measured would be: weight, height, blood pressure, HDL, LDL, fasting blood sugar at baseline and at week 6 and 12intervention. Depression and mania severity will be measured accordingly at the same times mentioned by Hamilton Depression scale and Young mania rating Scale respectively .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201208071556N44**
Registration date: **2012-08-26, 1391/06/05**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-08-26, 1391/06/05

Registrant information

Name

Shahin Akhondzadeh

Name of organization / entity

Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University Of Medical Sciences

Expected recruitment start date

2012-09-05, 1391/06/15

Expected recruitment end date

2014-09-06, 1393/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Melatonin on the components of metabolic syndrome in adolescent bipolarpatients taking risperidone plus lithium carbonate: a randomized,double blind, placebo-controlled clinical trial

Public title

Effect of Melatonin on the components of metabolic syndrome in adolescent bipolarpatients taking risperidone plus lithium carbonate

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1-Bipolar Disorder type 1(according to DSM-IV criteria) 2-age between 11-17 3- weight within normal range Exclusion criteria: 1-Active medical disease including seizure, hepatic disease, organic brain syndromes, Diabetes 2-history of metabolic syndrome 3-using appetizers such as antihistamines or appetite

suppressors like amphetamines 4-heavy consumption of Xantine drivatives(tea, coffee and cacao)

Age

From **11 years** old to **17 years** old

Gender

Both

Phase

2-3

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

Ethics Committee of Tehran University of Medical Sciences

Street address

Keshvarz Blvd

City

Tehran

Postal code

Approval date

2012-08-04, 1391/05/14

Ethics committee reference number

18139

Health conditions studied

1

Description of health condition studied

Bipolar disorder

ICD-10 code

F31

ICD-10 code description

Bipolar affective disorder

Primary outcomes

1

Description

Body Mass Index

Timepoint

Baseline and weeks 6-12 after beginig of treatment

Method of measurement

Calculated as body weight (kg) divided by the height in meters squared.

2

Description

High-density lipoprotein (HDL)

Timepoint

Baseline and weeks 6-12 after beginig of treatment

Method of measurement

Biochemistry

3

Description

Low- density lipoprotein

Timepoint

Baseline and weeks 6-12 after beginig of treatment

Method of measurement

Biochemistry

4

Description

Fasting blood sugar

Timepoint

Baseline and weeks 6-12 after beginig of treatment

Method of measurement

Biochemistry

5

Description

TG

Timepoint

Baseline and weeks 6-12 after beginig of treatment

Method of measurement

Biochemistry

6

Description

Blood pressure

Timepoint

Baseline and weeks 6-12 after beginig of treatment

Method of measurement

Mercury sphygmomanometer.

Secondary outcomes

1

Description

Severity of depression

Timepoint

Baseline and weeks 6 and 12 after startin treatment

Method of measurement
By Hamilton depression rating scale

2

Description
Severity of mania
Timepoint
Baseline and weeks 6 and 12 after startin treatment
Method of measurement
By Young mania rating scale

Intervention groups

1

Description
Intervention group:Tablet Risperidone plus lithium plus melatonin(3 mg/day) for 12 weeks
Category
Treatment - Drugs

2

Description
Tablet Risperidone plus lithium plus placebo for 12 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Roozbeh Hospital
Full name of responsible person
Dr. Shahin Akhondzadeh
Street address
South Kargar Sreeet, Roozbeh Hospital
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Prof. Akbar Fotouhi
Street address
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Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
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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