

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Melatonin on the components of metabolic syndrome in adolescent bipolar patients 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 12 intervention. 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)

Phone

+98 21 5541 2222

Email address

s.akhond@sina.tums.ac.ir

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 bipolar patients 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 bipolar patients 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 Sreet, 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

Keshvarz Blvd

City

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

Tehran University of Medical Sciences

Full name of responsible person

Prof. Shahin Akhondzadeh

Position

Prof. of Clinical Psychopharmacology

Other areas of specialty/work

Street address

Roozbeh Hospital; South Kargar street

City

Tehran

Postal code

Phone

+98 21 5541 2222

Fax

Email

s.akhond@sina.tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Prof. Shahin Akhondzadeh

Position

Prof. of Clinical Psychopharmacology

Other areas of specialty/work

Street address

Roozbeh Hospital, South Kargar Street

City

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

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Fax

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s.akhond@sina.tums.ac.ir

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