Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effect of lithium plus quetiapine with lithium plus risperidone in children and adolescents with bipolar Idisorder (manic or mixed episode) in a double blind randomized clinical trial

Protocol summary

Summary

The aim of this trial is to compare the effect of lithium plus quetiapine with lithium plus risperidone in children and adolescents with bipolar Idisorder (manic or mixed episode). In this randomized double blind trial, thirthy patients who will be hospitalized at razi psychiatric hospital will be nrecruited. Patients will be randomly allocated to lithium + quetiapine or lithium+ risperidone for a 6-week.Quetiapine dose is uo to 600mg/day and risperidone up to 6mg/ day. Patients will be assessed at baseline and after 2, 4 and 6 weeks. The primary efficacy measure is change in Yoing Mania Rating Scale score across the study period.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205059645N1**
Registration date: **2012-10-29, 1391/08/08**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-10-29, 1391/08/08

Registrant information

Name

Nastaran Habibi

Name of organization / entity

University of Social Welfare and Rehabilitation Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21334012209

Email address

na.habibi@uswr.ac.ir

Recruitment status

Recruitment complete

Funding source

University of Social Welfare and Rehabilitation Sciences

Expected recruitment start date

2012-07-22, 1391/05/01

Expected recruitment end date

2013-11-21, 1392/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of lithium plus quetiapine with lithium plus risperidone in children and adolescents with bipolar Idisorder (manic or mixed episode) in a double blind randomized clinical trial

Public title

The effect of quetiapine in children and adolescents with bipolar I disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: ages 10-17 with bipolar I disorder, manic or mixed episode Exclusion criteria: YMRS score < 20 (young mania rating scale); mood symptoms secondary to substance intoxication or withdrawal; substance use disorders 3 months prior to study; mental retardation; severe medical diseases; serious neurologic disorders; autistic disorder; history of hypersensitivity or intolerance or nonresponse to quetiapine or risperidone or lithium; use of long acting antipsychotics 3 months

prior to study; use of antidepressants or antipsychotics 1 week prior to study; use of psychostimulants or benzodiazepines 72 hours prior to study

Age

From **10 years** old to **17 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

University of Social Welfare and Rehabilitation Sciences

Street address

Kodakyar Ave., Daneshjo Blvd.,Evin

City

Tehran

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

7189/801/91/ت

Health conditions studied

1

Description of health condition studied

Bipolar disorder type I, manic or mixed episode

ICD-10 code

F31-1, F31

ICD-10 code description

Bipolar affective disorder, current episode manic without psychotic symptoms, Bipolar affective disorder, current episode manic with psychotic symptoms, Bipolar affective disorder, current episode mixed

Primary outcomes

1

Description

severity of manic or mixed episode

Timepoint

every two weeks

Method of measurement

Young Mania Rating Scale and Children's Depression Rating Scale

Secondary outcomes

1

Description

psychotic symptoms

Timepoint

every two weeks

Method of measurement

positive and negative syndrome scale - positive subscale

2

Description

general improvement

Timepoint

every two weeks

Method of measurement

clinical global impression-Improvement

3

Description

general functioning

Timepoint

baseline and endpoint

Method of measurement

children's global assessment scale

4

Description

extrapyramidal side effects

Timepoint

weeks 1,2,4,6

Method of measurement

simpson-angus extrapyramidal side effects scale, barnes akathisia scale, abnormal involuntary movement scale

5

Description

other side effects

Timepoint

weeks 1, 2, 4, 6

Method of measurement

side effects checklist

Intervention groups

1

Description
Intervention: lithium plus quetiapine up to 600 mg
Category
Treatment - Drugs

2

Description
control: lithium plus risperidone up to 6mg
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Child and Adolescent psychiatric unit at Razi Psychiatric hospital
Full name of responsible person
Nastaran Habibi
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of Social Welfare and Rehabilitation Sciences
Full name of responsible person
Nastaran Habibi
Street address
Kodakyar Ave., Daneshjo Blvd.,Evin
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
University of Social Welfare and Rehabilitation 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