

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Comparing efficacy and side effects of Memantine and Risperidone in treating autistic patients

Protocol summary

Summary

The purpose of this trial is to compare the efficacy and side effects of memantine and risperidone in autistic patients. Autistic patients between 4-17 years of age can enter this study. Exclusion criteria includes any history of neuroleptic malignant syndrome and a history of allergic reactions to risperidone or memantine. This study is a randomized, open label trial that will be done on 30 autistic patients. Starting dose of risperidone will be 0.02 mg/kg/day that rises to 0.04 mg/kg/day after 7 days and ultimately to 0.06 mg/kg/day at the beginning of week 3. Maximum daily dose of risperidone will be 3 mg/day. Starting dose of memantine will be 0.2 mg/kg/day that rises to 0.3 mg/kg/day after 7 days and ultimately to 0.4 mg/kg/day at the beginning of week 3. Maximum daily dose of memantine will be 20 mg/day. Baseline evaluation will be done by utilizing Aberrant Behavioral Check list and Childhood Autism Rating Scale scales. At the end of the fourth week reevaluation with Aberrant Behavioral Check list and at the end of 8th week reevaluation with both scales will be done.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204037202N5**

Registration date: **2012-06-20, 1391/03/31**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-06-20, 1391/03/31

Registrant information

Name

Padideh Ghaeli

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6695 4709

Email address

pghaeli@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing efficacy and side effects of Memantine and Risperidone in treating autistic patients

Public title

Comparing efficacy and side effects of Memantine and Risperidone in treating autistic patients

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: age of 4-17 year old; autistic patients not received any drug for treatment in past or not responded adequately to previous drugs; seizure attacks in epileptic patients should be controlled and any change in dose and kind of antiepileptic drugs should not be made from one month before entrance to the study. exclusion criteria: any neurologic disease except for

seizure; substance abuse; pregnancy; any history of neuroleptic malignant syndrome and history of allergic reactions to mementine or risperidone; history of cardiovascular diseases, malignant hematologic diseases, acute kidney or liver failure.

Age

From **4 years** old to **17 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not 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

Tehran University of Medical Sciences, Enghelab street

City

Tehran

Postal code

Approval date

2012-05-24, 1391/03/04

Ethics committee reference number

91-01-33-16991-51133

Health conditions studied

1

Description of health condition studied

Autism

ICD-10 code

F84

ICD-10 code description

Pervasive developmental disorders

Primary outcomes

1

Description

autism symptoms

Timepoint

before intervention, four and eight weeks after intervention

Method of measurement

Aberrant Behavioral Check list and Childhood Autism Rating Scale scales

Secondary outcomes

1

Description

Side effects including any side effect that related to the drug

Timepoint

two, four and eight weeks after intervention

Method of measurement

side effects checklist

Intervention groups

1

Description

Risperidone with gradual increasing in dose will be prescribed as bellow: 0.02mg/kg/day at beginning, 0.04 mg/kg/day at second week and ultimately will be increased to 0.06 mg/kg/day at third week. Calculated dose based on body weight will be rounded to the nearest dose that according to the available dosage form of risperidone can easily be prescribed. Maximum daily dose of risperidone will be 3 mg.

Category

Treatment - Drugs

2

Description

Memantine with gradual increasing in dose will be prescribed as bellow: 0.2mg/kg/day at beginning, 0.3mg/kg/day at second week and ultimately will be rised to 0.4mg/kg/day at third week. Calculated dose based on body weight will be rounded to the nearest dose that according to the available dosage form of memantine can easily be prescribed. Maximum daily dose of memantine will be 20 mg.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric and adolescent psychiatrist office
Full name of responsible person
Mehdi Tehranidoost
Street address
Baran Building, Falsafi alley, Shariati avenue
City
Tehran

2

Recruitment center
Name of recruitment center
Clinic of psychiatric diseases in pediatrics and adolescents
Full name of responsible person
Zahra Shahrivar
Street address
Roozbeh hospital, South Kargar avenue
City
Tehran

3

Recruitment center
Name of recruitment center
Pediatric and adolescent psychiatrist office
Full name of responsible person
Javad Alagheband Rad
Street address
Sharifi alley, Behzad street, Mirdamad boulevard
City
Tehran

4

Recruitment center
Name of recruitment center
Psychiatric diseases hospital
Full name of responsible person
Padideh Ghaeli
Street address
Roozbeh hospital, South Kargar avenue
City
Tehran

5

Recruitment center
Name of recruitment center
Psychiatric diseases hospital
Full name of responsible person
Naemeh Nikvarz
Street address
Roozbeh hospital, South Kargar avenue
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Tehran University of Medical Sciences
Full name of responsible person
Akbar Fotouhi
Street address
Central building of Tehran University of Medical Sciences, Ghods street
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
Naemeh Nikvarz
Position
Clinical Pharmacy resident
Other areas of specialty/work
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Person responsible for scientific inquiries

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Clinical Pharmacist
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Tehran University of Medical Sciences

Full name of responsible person

Naemeh Nikvarz

Position

Clinical Pharmacy resident

Other areas of specialty/work**Street address**

Faculty of Pharmacy and Pharmaceutical sciences, 16
Azar street

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