# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## Assessment the efficacy of augmentation Flavonoid Quercetin to risperidon in treatment of autism spectrum disorders

## Protocol summary

**Summary**

(1) Objectives: Assessment he efficacy of augmentation Flavonoid Quercetin to risperidon in treatment of autism spectrum disorders. (2) Participants including major eligibility criteria: Eligible patients after gaining the consent of a parent or legal guardian patients will be enrolled. Patients who had organic disease, patients have been treated with other psychotropic drugs and also patients with other psychiatric disorders are excluded (3 ) Autism spectrum disorders 3-12 years old , The samples were randomly divided into two groups of 35 persons.(4) Intervention: Both groups were treated with Risperidone prior to entering the study, first group is treated with placebo and the second group is treated with Flavonoid Quercetin , Patients at weeks zero, six, towelve in terms of therapeutic effects and adverse drug reactions are evaluated. Results of the study will be assessed by CARS, CGI questionnaire and check list of drugs side effects (5) Main outcome measures (variables): Severity of Autism

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2017013132326N1**
Registration date: **2017-04-06, 1396/01/17**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**

2017-04-06, 1396/01/17

**Registrant information**

**Name**

Narges Nejati Fard

**Name of organization / entity**

Mashhad University of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

+98 51 3601 6683

**Email address**

nejatifardn931@mums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

Vice Chancellor for Research of Mashhad University of Medical Sciences

**Expected recruitment start date**

2017-03-05, 1395/12/15

**Expected recruitment end date**

2017-11-06, 1396/08/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Assessment the efficacy of augmentation Flavonoid Quercetin to risperidon in treatment of autism spectrum disorders

**Public title**

The efficacy of augmentation Flavonoid Quercetin to risperidon in treatment of autism spectrum disorders

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

The inclusion criteria: Of all patients with ASD, ranging in age from 3to 12years; Parent's Consent; No obvious organic disease; The lack of other psychiatric disorders; Not taking other psychoactive medications other than risperidone; IQ higher than 50 on the basis of Weiland test. The exclusion criteria: In the absence of cooperation

of parents after inclusion; the risk of any side effect or another disease that cause a problem in results.

**Age**
From **3 years** old to **12 years** old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **70**

**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**
Ethical Committee of Mashhad University of Medical Sciences

**Street address**
Qoreishi Building, Daneshgah St

**City**
Mashhad

**Postal code**
1394491388

**Approval date**
2017-01-11, 1395/10/22

**Ethics committee reference number**
IR.MUMS.fm.REC.1394.459

## Health conditions studied

### 1

**Description of health condition studied**
Autism Spectrum Disorders

**ICD-10 code**
F84

**ICD-10 code description**
Pervasive developmental disorders

## Primary outcomes

### 1

**Description**
Severity of Autism

**Timepoint**
Previous the syudy, 6 weeks after study, 12 weeks after study.

**Method of measurement**
CARS test,CGI test

### 2

**Description**
Response to treatment

**Timepoint**
Previous the syudy, 6 weeks after study, 12 weeks after study.

**Method of measurement**
CARS test,CGI test

## Secondary outcomes

### 1

**Description**
Drug's side effect

**Timepoint**
Previous the study, 6weeks after study, 12weeks after study

**Method of measurement**
Check list

## Intervention groups

### 1

**Description**
The intervention group have been treated with risperidone(maximum dose 2 mg) is also treated with placebo. The duration of intervention is 12 weeks.

**Category**
Treatment - Drugs

### 2

**Description**
The intervention group have been treated with risperidone (maximum dose 2mg ), is also treated with Flavonoid Quercetin . Dosing and titration of the drug individually, but the total dose of Flavonoid Quercetin is75 mg per10 kg at the start ,(PO) and the duration of intervention is 12weeks.

**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Outpatient Clinic

**Full name of responsible person**
Dr Narges Nejati Fard
**Street address**
Ibne Sina Hospital
**City**
Mashhad

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Vice Chancellor for Research of Mashhad University of Medical Sciences
**Full name of responsible person**
Dr Mahyar Mirheydari
**Street address**
Qoreishi Building, Daneshgah St
**City**
Mashhad
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Vice Chancellor for Research of Mashhad 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**
Mashhad University of Medical Siences
**Full name of responsible person**
Dr Narges Nejati Fard
**Position**
Psychiatric Resident
**Other areas of specialty/work**
**Street address**
Ibn e Sina Hospital
**City**
Mashhad
**Postal code**
**Phone**
+98 51 3711 2721
**Fax**
**Email**
nejatifardn931@mums.ac.ir
narges_nejatee@yahoo.com
**Web page address**

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Mashhad University of Medical Sciences
**Full name of responsible person**
Dr Paria Hebrani
**Position**
Associate Professor
**Other areas of specialty/work**
**Street address**
Ibn e sina Hospital
**City**
Mashhad
**Postal code**
**Phone**
+98 51 3711 2722
**Fax**
**Email**
Hebranip@mums.ac.ir
**Web page address**

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Mashhad University of Medical Sciences
**Full name of responsible person**
Dr Narges Nejati fard
**Position**
Psychiatric Resident
**Other areas of specialty/work**
**Street address**
Ibn e Sina Hospital
**City**
Mashad
**Postal code**
**Phone**
**Fax**
**Email**
**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*