

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The prevalence of side effect of Risperidone drug in patient with schizophrenia

Protocol summary

Summary

The aim of this before after study was to determine the prevalence of side effect of Risperidone in the patients with schizophrenia. A total of 50 patients with schizophrenia referred to Shahid Mofateh psychiatry Clinic of Yasouj city, aged 15-60 years old, without any other diseases and no drug consumption in 6 months prior to the study first visit were recruited and received Risperidone for 1 month duration with dosage between 1 and 10 mg per day; prescribed by a psychiatrist based on the patient's condition. The patients were visited by a psychiatrist every 15 days and interview, MSE, and physical examination was done to determine if any adverse effect occurred.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011225147N2**

Registration date: **2011-02-16, 1389/11/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-02-16, 1389/11/27

Registrant information

Name

Nazir Hashemi Mohammad Abad

Name of organization / entity

Yasuj University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 74 1222 4696

Email address

n-hashemi@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

Yasouj University of Medical Sciences

Expected recruitment start date

2010-04-04, 1389/01/15

Expected recruitment end date

2010-09-06, 1389/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The prevalence of side effect of Risperidone drug in patient with schizophrenia

Public title

The prevalence of side effect of Risperidone drug in patient with schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: the diagnosis of schizophrenia by a psychiatrist based on DSMIV-TR criteria, age 15 – 60 years, no history of use of any other drug over 6 months prior to the study, no history of any other systemic diseases such as epilepsy, hematological diseases, CVD, glaucoma Exclusion criteria: poor cooperation, not coming for visits, incidence of serious side effects

Age

From **15 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Yasouj University of Medical sciences

Street address

Yasouj University of Medical Sciences, Jomhoori Islami Boulevard, Yasouj

City

Yasouj

Postal code**Approval date**

2009-03-09, 1387/12/19

Ethics committee reference number

871219

Health conditions studied**1****Description of health condition studied**

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes**1****Description**

Incidence of adverse effects

Timepoint

two times: 15 days and 30 days after intervention

Method of measurement

Visiting by psychiatrist based on interview, mental status examination, filling questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Risperidone, with dosage between 1 and 10 mg per day; prescribed by a psychiatrist based on the patient's condition, for 1 month

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Mofateh Clinic of Yasouj

Full name of responsible person

Nazir Hashemi Mohammad Abad

Street address

No 19, Bahonar 5 St., Oghab square

City

Yasouj

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Yasouj University of Medical Sciences

Full name of responsible person

Nazir Hashemi Mohammad Abad

Street address

No 19, Bahonar 5 St., Oghab square

City

Yasouj

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Yasouj 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

Yasouj University of Medical sciences

Full name of responsible person

Nazir Hashemi Mohammad Abad

Position

Assistant professor of Yasouj University of Medical sciences- psychiatrist

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Position

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Fax

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