

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of Serum Prolactin Concentrations after Administration of Long-Acting Injectable Risperidone and Oral Risperidone Tablets in Patients with Psychotic Disorders

Protocol summary

Study aim

Comparison of the effect of long-acting injectable risperidone and oral risperidone tablets on serum prolactin concentration

Design

Phase 3 randomized parallel group clinical trial on 60 patients who will be divided into two groups of 30 people by simple randomization and using a table of random numbers.

Settings and conduct

60 patients with psychotic disorders who are hospitalized in Rey Town Razi Psychiatric Hospital will be randomly divided into two groups of 30 and will be treated with oral risperidone (with a therapeutic dose of 4-6 mg daily) or long-acting injectable risperidone (Two injections of 25 mg suspension on the first and seventh days). Baseline serum prolactin concentration will be measured before starting the treatment and after starting the treatment on the first day, the seventh day and the fourteenth day. Also, due to the metabolic side effects of antipsychotic drugs, the blood sugar level and fat profile of the patients will be measured before the start of the treatment and after that on the fourteenth day.

Participants/Inclusion and exclusion criteria

Patients aged 18 to 60 with psychotic disorders who are candidates for receiving antipsychotic drugs and have not used these drugs in the last year can enter the study. Pregnant women and those with thyroid, kidney, liver or high prolactin function tests will not be included in the study.

Intervention groups

The first group will be treated with oral risperidone and the second group will be treated with long-acting injectable risperidone.

Main outcome variables

Serum prolactin level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221003056082N1**

Registration date: **2023-01-11, 1401/10/21**

Registration timing: **prospective**

Last update: **2023-01-11, 1401/10/21**

Update count: **0**

Registration date

2023-01-11, 1401/10/21

Registrant information

Name

Marjan Molaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7173 2000

Email address

dr.marjanmolaei@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-04, 1401/11/15

Expected recruitment end date

2023-08-06, 1402/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Serum Prolactin Concentrations after Administration of Long-Acting Injectable Risperidone and Oral Risperidone Tablets in Patients with Psychotic Disorders

Public title

Effect of Oral and Injectable Risperidone on Prolactin in Psychotic Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 60 years Having a psychotic disorder No mood disorder A candidate for antipsychotics Not using antipsychotic drugs in the last year Patient satisfaction and cooperation

Exclusion criteria:

Patients with high prolactin levels Patients with hypothyroidism Patients with impaired liver or kidney tests Pregnant women

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling is done by simple random sampling. First, among hospitalized patients, we select 60 patients who meet the entry criteria and prepare a list of names in alphabetical order and divide the patients into two desired groups using random number table software. Thus, for each person, if a random number between zero and 0.5 is determined, they enter the oral group, and if a number greater than half is determined, they enter the injectable group.

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 University of Rehabilitation Sciences and Social Health

Street address

Kudakyar Deadend, Daneshju Blvd, Evin

City

Tehran

Province

Tehran

Postal code

1985713834

Approval date

2022-09-21, 1401/06/30

Ethics committee reference number

IR.USWR.REC.1401.089

Health conditions studied

1

Description of health condition studied

The effect of oral and injectable risperidone on serum prolactin level

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Serum prolactin level

Timepoint

Before starting the treatment and on the first day, the seventh day and the fourteenth day after starting the treatment with oral or injectable risperidone

Method of measurement

Prolactin laboratory kit

Secondary outcomes

1

Description

Fasting blood sugar

Timepoint

Before the intervention and on the fourteenth day after the intervention

Method of measurement

Blood sugar laboratory kit

2

Description

Blood triglycerides

Timepoint

Before the intervention and on the fourteenth day after the intervention

Method of measurement

Triglyceride laboratory kit

3

Description

Blood cholesterol

Timepoint

Before the intervention and on the fourteenth day after the intervention

Method of measurement

Cholesterol laboratory kit

Intervention groups

1

Description

The first intervention group: Oral risperidone 2 mg two or three times a day for two weeks

Category

Treatment - Drugs

2

Description

The second intervention group: Long-acting injectable risperidone 25 mg on the first and seventh days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Razi Psychiatric Hospital

Full name of responsible person

Dr.Ali Nazeriastaneh

Street address

Rastegar Blvd., Varamin Road., Rey Town

City

Tehran

Province

Tehran

Postal code

1867612016

Phone

+98 21 3340 1220

Email

razi.pr@uswr.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

University of social welfare and rehabilitation sciences

Full name of responsible person

دکتر علی ناطری آستانه

Street address

Kudakyar Deadend, Daneshju Blvd, Evin

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webmaster@uswr.ac.ir

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

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact**Name of organization / entity**

University of social welfare and rehabilitation sciences

Full name of responsible person

Dr.Ali Nazriastaneh

Position

associate professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

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Position

associate professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for updating data

Contact

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Marjan Molaei

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to

make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Participants data file: After unrecognizing the individuals, the section on the main outcome and results of the study will be published and other information will be kept by the researcher and will be available to other researchers if needed. Study protocol: How to do the study in detail will be published. Informed consent form: The raw form will be published, but the form related to each patient can not be published due to the fact that it contains the patient's name and some personal information, but will remain with the researcher. Clinical study report: The result of the study will be published in a transparent manner along with the result of statistical analysis

When the data will become available and for how long

6 months after the end of the study and the final analysis, the initial information will be published, the final results will be available at the same time as the results are published.

To whom data/document is available

Access to the research project is based on the university mechanism and the rules of the educational center and is available for academic and scientific institutions. If the article is published, the results will be available to the public (subject to the rules of the relevant journal)

Under which criteria data/document could be used

Access to non-personally identifiable data and other documents is under the supervision of the University Ethics Committee and at the discretion of that authority, will be accessible in a limited way for additional research.

From where data/document is obtainable

Applicants can go in person to the psychosis research center affiliated with the University of Rehabilitation Sciences and Social Health located in Razi Psychiatry Hospital at the address of shahid Rastegar Blvd, Varamin Road, Rey Town., or contact the director of the center, Dr. Ali Nazeriastaneh, and the expert of the center, Mr. Bakhtevan, through phone number 021-33401220-29. They can also email their request to psychosisc@uswr.ac.ir. Additional information is available on the center's website at psychosis.uswr.ac.ir.

What processes are involved for a request to access data/document

Submitting an application to the Psychosis Research Center, reviewing the application by the university's ethics committee, if approved by the university as well as obtaining approval and consent from the lead researcher regarding the use of data in another study, documents will be available.

Comments