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 ناظری آستانه
Street address
Kudakyar Deadend, Daneshju Blvd, Evin
City
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Tehran
Postal code
1985713834
Phone
+98 21 7173 2000
Email
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

Contact
Name of organization / entity
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Full name of responsible person

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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 unrecognizabling 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. Bakhtevar, through phone number 021-33401220-29. They can also email their request to psychosisrc@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