Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Adjunctive treatment with Aripiprazole for Risperidone –induced hyperprolactinemia

Protocol summary

Summary

The psychotic women with good response to risperidone that the change to clozapine isn't possible, entered to study. The aim of this study is treatment of risperidone induced hyperprolactinemia. The main criterias of inclusion to study are women in reproductive age and hyperprolactinemia and criterias of exclusion are previous amenorrhea, breastfeeding, pregnancy and past history of seizure …. In these patients, the serum prolactine is measured in initial phase of study and monthly for three months. in prolactine levels of greater than 200 mg/dl or appearance of hyperprolactinemia symptoms and signs , aripiprazole is added on risperidone. Then serum prolactine level is meseaured weekly for 2 weeks and monthly for 3 months. Anti psychotic side effects such as weight are determined before initiation of aripiprazole and then monthly for three months. The primary sample size of this study are 40 patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307182181N6**
Registration date: **2013-07-28, 1392/05/06**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-07-28, 1392/05/06

Registrant information

Name

Fatemeh Ranjbar Kouchaksaraei

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

research deputy

Expected recruitment start date

2012-11-21, 1391/09/01

Expected recruitment end date

2013-11-21, 1392/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Adjunctive treatment with Aripiprazole for Risperidone –induced hyperprolactinemia

Public title

Adjunctive treatment with Aripiprazole for Risperidone –induced hyperprolactinemia

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criterias : 1.hyperprolactinemia 2. women in reproductive age 3.candidate for risperidone continuation exclusion criterias: 1.previous amenorrhea 2.breastfeeding 3.pregnancy 4.renal failure 5. hypothyroidism 6. pituitary tumors 7. consumption of methyldopa, levodopa,cimethidine, strogen, opium derivatives

Age

From **20 years** old to **49 years** old

Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
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
research deputy
Street address
golgasht Ave.
City
tabriz
Postal code
Approval date
2012-11-21, 1391/09/01
Ethics committee reference number
5/4/7828

Health conditions studied

1

Description of health condition studied
hyperprolactinemia induced by risperidone
ICD-10 code
E22.1
ICD-10 code description
Hyperprolactinaemia

Primary outcomes

1

Description
serum prolactin level
Timepoint
weekly for first 2 weeks then monthly for 3 months
Method of measurement
mg/dl

Secondary outcomes

1

Description
drug side effect
Timepoint
the end of study
Method of measurement
patient interview

Intervention groups

1

Description
aripiprazole is added on risperidone if : 1. serum prolactine > 200 mg/dl or 2.appearing any symptoms or signs of hyperprolactinemia
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
razi hospital
Full name of responsible person
dr fatemeh ranjbar kouchaksaraei
Street address
elgoli Ave.
City
tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
tabriz university of medical science
Full name of responsible person
research deputy
Street address
golgasht Ave
City
tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
tabriz university of medical science
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

razi hospital

Full name of responsible person

Fatemeh Ranjbar Kouchaksaraei

Position

associate professor

Other areas of specialty/work

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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