

# 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 meseasured 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)

##### Phone

+98 41 1337 6923

##### Email address

ranjbarf@tbzmed.ac.ir

##### 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 methyl dopa, 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 &gt; 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**

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**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  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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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*