

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Effect of Aspirin augmentation on cognitive & clinical symptoms of schizophrenic patients

#### Protocol summary

##### Summary

NSAID drugs inhibit prostaglandin synthesis by inactivation of cyclooxygenase and are effective in this way. Inhibitors of non-selective COX such as aspirin, with protective effect on the heart are preferred. Also non-selective COX inhibitor range effects are higher due to inhibition of both enzymes COX1 and COX2. 40 patients admitted to Ibn Sina hospital of Mashhad are included in this research. Baseline includes demographic data for patients, the PANSS test to assess psychological symptoms, wechser, Wisconsin, stroop, BPRS and digit span tests to assess cognitive status. Evaluations are made as a double-blind in two groups to control the symptoms of psychosis under treatment with risperidone . Dose of risperidone started with 2mg and within a week titrated to 6mg or maximum dose tolerated by the patient. Patients were randomly divided into two groups and the treatment of the first group starts with 1000mg aspirin (500mg aspirin daily, Abidi company) and the placebo group with 2 tablets resembling 500mg aspirin daily. Clinical and cognitive evaluations are repeated at weeks 3, 6 and 12. In each patient, the drug complication will be examined. Patients entered into research: - diagnosis of schizophrenia based on DSM-IV - PANSS score at the beginning of the project is more than 60. - Between 3-1 episodes or less than 5 years of disease duration. Exclusion criteria: - Need to be using other drugs. (Anticholinergics and benzodiazepines are except)

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201109287660N1**

Registration date: **2012-11-08, 1391/08/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-11-08, 1391/08/18

##### Registrant information

###### Name

Maryam Tavakoli

###### Name of organization / entity

Mashhad University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 1761 1849

###### Email address

tavakolim881@mums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Mashhad University of Medical Sciences

##### Expected recruitment start date

2012-04-03, 1391/01/15

##### Expected recruitment end date

2012-11-05, 1391/08/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Aspirin augmentation on cognitive & clinical symptoms of schizophrenic patients

##### Public title

Effect of Aspirin in schizophrenia

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: 1 - Is based on DSM-IV diagnosis of

schizophrenia. 2 - The patient or patient's guardian consent to participate. 3 - PANSS score at the beginning of the project is more than 60. 4 - less than 5 years of disease duration and between 3 to 1 episodes. 5 - No physical disease based on clinical examination. 6 - Chronic NSAID is not used. 7 - Not taking corticosteroids. 8 - Not pregnant. 9 - there is no contraindication for aspirin and omeprazole. Exclusion criteria: 1 - Sensitivity to the drug 2 - Patients who choose to be excluded. 3 - Require other drugs. (Anticholinergics and benzodiazepines are excepted) 4 - Where ECT is needed.

#### **Age**

No age limit

#### **Gender**

Both

#### **Phase**

3

#### **Groups that have been masked**

No information

#### **Sample size**

Target sample size: 40

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Mashhad University of Medical Sciences

###### **Street address**

Ghoreishi Building ,Daneshgah Street

###### **City**

Mashhad

###### **Postal code**

##### **Approval date**

2011-09-18, 1390/06/27

##### **Ethics committee reference number**

89921

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

schizophrenia

##### **ICD-10 code**

F20.0

##### **ICD-10 code description**

Paranoid schizophrenia

### **Primary outcomes**

#### **1**

##### **Description**

cognitive disorders

##### **Timepoint**

baseline and 3th,6th,12th weeks

##### **Method of measurement**

cognition tests

#### **2**

##### **Description**

clinical symptoms

##### **Timepoint**

baseline and 3th,6th,12th weeks

##### **Method of measurement**

PANSS

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

##### **Description**

Case group:Tab Aspirin 500 mg ,BID( Abidi company)

##### **Category**

Placebo

#### **2**

##### **Description**

placebo group: tab placebo Aspirin like 500 mg ,BID

##### **Category**

Treatment - Drugs

### **Recruitment centers**

#### **1**

##### **Recruitment center**

###### **Name of recruitment center**

Psychitric Ibne\_Sina Hospital

###### **Full name of responsible person**

Dr. Maryam Tavakoli

###### **Street address**

Ferdosi Sq, Hore Ameli Blvd

###### **City**

Mashhad

### **Sponsors / Funding sources**

## 1

### Sponsor

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Miss Ardekanian

**Street address**

Ghoreishi Building, Daneshgah Street

**City**

Mashhad

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mashhad 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**

Psychiatric Ibnesina Hospital

**Full name of responsible person**

Dr. Maryam Tavakoli

**Position**

Psychiatric resident

**Other areas of specialty/work**

**Street address**

Hore Ameli Blvd, Ferdosi Sq.

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### Person responsible for scientific inquiries

**Contact**

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**Full name of responsible person**

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### Person responsible for updating data

**Contact**

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Psychiatric Ibnesina Hospital

**Full name of responsible person**

Dr. Maryam Tavakoli

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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*