

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

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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