Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 2026

Effect of Adding Aspirin to Antipsychotic Treatment on Severity of Symptoms in Schizophrenic Patients

Protocol summary

Summary

This was a triple blind, prospective clinical trial study. The population included patients with schizophrenia based on clinical interview and DSM-IV-TR within the age group of 18-65 years old referred to Noor Hospital psychiatric clinic or emergency. The purpose of this project, methods and frequency of follow-up were entirely explained to the patients or their legal guardians. The subjects participated upon their written consent. The inclusion criteria were age of 18-65 years old, diagnosed with schizophrenia based on clinical interview and DSM-IV-TR, patients with 2 years of history since the onset of the disease. The exclusion criteria were unwillingness to participate in the study, failure to see doctor for follow-up for whatever reason, unstable medical illness and medical history, contra indications for use of aspirin, such as asthma or seasonal allergies, ulcers, kidney disease, active bleeding or clotting of blood disorders such as hemophilia or bleeding, gout, nasal polyps, chronic use of NSAID, concomitant use of corticosteroids for any reason and maternity. The patients were randomly through a number table divided into three groups of 20 members labeled intervention 1, intervention 2 and control. Patients in each group were initially evaluated through PANSS scale in terms of severity of schizophrenia symptoms. At baseline, clinical evaluation involved cell count, liver function, kidney, thyroid and cardiac function tests. Moreover, the cardiac status was assessed through routine ECG. The patients were then referred to a psychiatrist who prescribed medication. In addition to antipsychotic medication, intervention 1 received daily aspirin produced by Daroupakhsh Co for 6 weeks at a dose of 500 mg, while intervention 2, in addition to antipsychotic medication, received daily aspirin with a dose of 325 mg for 6 weeks. The control, in addition to antipsychotic medication, received daily placebo for 6 weeks for 6 weeks. It should be noted the placebo had been produced in the same shape and color of the effective aspirin. Drug and placebo were coded A, B, and C. In order to reduce the gastrointestinal side effects, Omeprazole 20 mg daily was given to each patient. Neither the examiner nor the clinician and the patient were aware of the drug compounds since they were labeled A, B, and C. The PANSS scale was administered on the first day, the end of the sixth week and one month after cessation of aspirin or placebo, followed by recording and comparing the scores. The data were analyzed through SPSS 20, and based on descriptive statistics of frequency distribution, mean and standard deviation. Moreover, the results of the test were compared through Repeated Measure and logistic regression.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016010725892N1**
Registration date: **2016-02-05, 1394/11/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-02-05, 1394/11/16

Registrant information

Name

Asefeh Mojdeh

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 31 3222 2475

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Recruitment status

Recruitment complete

Funding source
Isfahan University of Medical Sciences

Expected recruitment start date
2014-06-22, 1393/04/01
Expected recruitment end date
2015-06-22, 1394/04/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Adding Aspirin to Antipsychotic Treatment on Severity of Symptoms in Schizophrenic Patients

Public title
Effect of aspirin on schizophrenia
Purpose
Treatment
Inclusion/Exclusion criteria
The inclusion criteria were age of 18-65 years old; diagnosed with schizophrenia based on clinical interview and DSM-IV-TR; patients with 2 years of history since the onset of the disease. The exclusion criteria were unwillingness to participate in the study; failure to see doctor for follow-up for whatever reason; unstable medical illness and medical history; contraindications for use of aspirin, such as asthma or seasonal allergies, ulcers, kidney disease, active bleeding or clotting of blood disorders such as hemophilia or bleeding, gout, nasal polyps; chronic use of NSAID; concomitant use of corticosteroids for any reason and maternity.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences, Hezar Jarib Street
City
Isfahan
Postal code
Approval date
2013-09-23, 1392/07/01
Ethics committee reference number
393259

Health conditions studied

1

Description of health condition studied
Schizophrenia
ICD-10 code
F20
ICD-10 code description
Schizophrenia

Primary outcomes

1

Description
PANSS test
Timepoint
On the first day, at the end of the sixth week and one month after cessation of aspirin or placebo
Method of measurement
PANSS test

Secondary outcomes

empty

Intervention groups

1

Description
In addition to antipsychotic medication, intervention 1 received daily aspirin produced by Daroupakhsh Co for 6 weeks at a dose of 500 mg, while intervention 2, in addition to antipsychotic medication, received daily aspirin with a dose of 325 mg for 6 weeks. The control, in addition to antipsychotic medication, received daily placebo for 6 weeks for 6 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Noor Hospital Psychiatric clinic and emergency ward
Full name of responsible person
Dr. Asefeh Mojdeh, psychiatriy resident
Street address
Noor hospital, Otandari st., Isfahan
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Prof. Mehdi Nematbakhsh
Street address
Isfahan University of Medical Sciences, Hezar Jarib St.
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahan 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
Isfahan University of Medical Sciences
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Asefeh Mojdeh
Position
MD, Psychiatric resident
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Person responsible for updating data

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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