Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Spironolacton as adjunctive treatment of symptoms in patients with schizophrenia: a double blind and placebo controlled trial

Protocol summary

Study aim
The objective of this randomized, double-blind, placebo controlled study is to test the hypothesis that the addition of spironolacton would improve psychopathology in subjects with schizophrenia

Design
randomized, double-blind, placebo controlled study
method of randomization: Random permuted Block
Sample size: 52 Trial phase: 3

Settings and conduct
The study will be conducted among patients attending Qods Psychiatric Hospital-Sanandaj. Patients with schizophrenia who have admitted in Qods Hospital will be included in the trial provided the inclusion criteria will be met,

Participants/Inclusion and exclusion criteria
Inclusion criteria:1-Diagnosis of Schizophrenia based on DSM-5 criteria; 2- Age between 18-55; 3-Chronic Schizophrenia- duration of the disorder more than 2 years; 4-Minimum score of 20 in negative sub score. 5-being stable on an antipsychotic for the last 2 months(6 months for clozapin) Exclusion criteria:1-Any serious medical or neurological problem; 2- IQ less than 70; 3-Substance dependence during the last 6 months(except for nicotine and caffeine); 4-receiving ECT during the last 2 months ; 6-Acute or chronic systemic diseases; 7-History of neurosurgery; 8- History of head trauma 9-allergy to spironolactone 10-receiving mood stabilizers 11.gynecomastia

Intervention groups
Intervention group:regular antipsychotic combined with 100mg/day spironolacton as intervention group for 8 weeks Control group: regular antipsychotic plus placebo for 8 weeks

Main outcome variables
Severity of schizophrenia

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20091229002935N8**
Registration date: **2019-12-07, 1398/09/16**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-07, 1398/09/16**
Update count: **0**

Registration date
2019-12-07, 1398/09/16

Registrant information

Name
Farzin Rezaei

Name of organization / entity
Kurdistan University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 87 1356 1822

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farrezaei@muk.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-11-21, 1398/08/30

Expected recruitment end date
2020-09-21, 1399/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Spironolacton as adjunctive treatment of symptoms in patients with schizophrenia: a double blind and placebo controlled trial

Public title
Spironolacton as adjunctive treatment of negative symptoms in patients with schizophrenia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of Schizophrenia based on DSM-5 criteria Age between 18-55 years old Chronic Schizophrenia- duration of the disorder more than 2 years Minimum score of 20 in negative sub score being stable on antipsychotic for the last 2 months(6 months for clozapine)

Exclusion criteria:
Any serious medical or neurological problem IQ less than 70. Substance dependence during the last 6 months(except for nicotine and caffeine) receiving ECT during the last 2 months Acute or chronic systemic diseases History of head trauma exacerbation of symptoms(developing the active phase) hypersensitivity to spironolacton post-psychotic depression gynecomastia

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **52**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants allocated to intervention or control group via Random permuted blocks (each block has four cases): AABB, ABAB, BBAA, BABA A:Intervention Group B:Control Group

Blinding (investigator's opinion)
Double blinded

Blinding description
The participants, clinicians and outcome evaluators will be blind regarding grouping and receiving placebo

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Kurdistan University of Medical Sciences

Street address
No 1, Pasdaran Blvd.Kurdistan University of Medical Sciences, Sanandaj

City
Sanandaj

Province
Kurdistan

Postal code
1344666177

Approval date
2019-09-30, 1398/07/08

Ethics committee reference number
IR.MUK.REC.1398.144

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
Severity of schizophrenia

Timepoint
Baseline and weeks 2-4-8 after beginning of treatment

Method of measurement
by Positive and Negative Symptoms Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Antipsychotic medication combined with 100 mg/day spironolacton as intervention group for 8 weeks

Category
Treatment - Drugs

2

Description

Control group: An antipsychotic combined with placebo as control group for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Qhods hospital- Sanandaj

Full name of responsible person

Dr Farzin Rezaei

Street address

Pasdaran Blvd- Qhods hospital - Sanandaj

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Dr Ebrahim Ghaderi

Street address

Deputy of research, Kurdistan university of Medical Sciences, Pasdaran Blvd., Sanandaj

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sanandaj University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Farzin Rezaei

Position

Associate professor of psychiatry

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
All data will be distributed through final report

When the data will become available and for how long
from 2021 to 2026

To whom data/document is available
academic researchers

Under which criteria data/document could be used
by email

From where data/document is obtainable
Dr Farzin Rezaei

What processes are involved for a request to access data/document
farrezaei@muk.ac.ir

Comments