

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Investigating the effectiveness of adding famotidine and vitamin B6 to standard drug treatment in reducing negative symptoms in patients with schizophrenia disorder: a clinical trial with a control group

Protocol summary

Study aim

Determine effectiveness of adding famotidine and vitamin B6 to standard pharmaceutical treatment in patients with schizophrenia disorder

Design

Clinical trials with control group, parallel groups, double-blind, randomized, phase 3, on 80 patients, Randomization was centralized and computerized with concealed randomization sequence carried out at an external site.

Settings and conduct

This study is a double-blind trial. The study sample population consists of all male and female with schizophrenia disorder referring to Farabi Hospital in Kermanshah, that 80 persons will be selected in the available method and randomly will be divided into two groups. Pills will be given to patients without awareness of the patient and the examiner, and the code for each drug will be recorded in the patient's questionnaire. All subjects in all two groups will be re-evaluated by completing questionnaires at baseline, 6 weeks and the end of the study (12 weeks after baseline), will be assessed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Both genders; Schizophrenia Disorder diagnoses with negative symptoms according to Diagnostic and Statistical Manual of Mental Disorders fifth edition by a psychiatrist; under treatment with aripiprazole. Non-inclusion criteria: Patients who are not agree to participate in the study

Intervention groups

Intervention group: The group will receive the combination of famotidine/vitamin B6 tablets in 12 weeks, along with the standard drug treatment (aripiprazole). The daily dose will be 1 pill of 190 mg (famotidine, 40 mg and vitamin B6, 150 mg). These pills will be given to patients without awareness of the patient

and the examiner, and the code for each drug will be recorded in the patient's questionnaire.

Famotidine/vitamin B6 pills will be purchased from Caspin Daru Pharmaceutical Company.

Main outcome variables

Severity of negative symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150822023705N16**

Registration date: **2023-04-17, 1402/01/28**

Registration timing: **prospective**

Last update: **2023-04-17, 1402/01/28**

Update count: **0**

Registration date

2023-04-17, 1402/01/28

Registrant information

Name

Mostafa Alikhani

Name of organization / entity

Kermanshah University of Medical Sciences -
Substance Abuse Prevention Research Center

Country

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+98 838264513

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-10, 1402/02/20
Expected recruitment end date
2023-08-05, 1402/05/14
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effectiveness of adding famotidine and vitamin B6 to standard drug treatment in reducing negative symptoms in patients with schizophrenia disorder: a clinical trial with a control group

Public title
The effectiveness of adding famotidine and vitamin B6 to standard drug treatment in patients with schizophrenia disorder

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Schizophrenia Disorder diagnoses with negative symptoms according to Diagnostic and Statistical Manual of Mental Disorders fifth edition by a psychiatrist under treatment with aripiprazole
Exclusion criteria:
Disagreement to participate in the study

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be divided into two equal groups (A and B) based on a randomized size 8-block design using random allocation software. To randomly assign 80 patients to the intervention and control groups, 8 different blocks of 10 different letters A and B, which indicate Famotidine/vitamin B6 and placebo groups respectively, will be initially created. These blocks will be numbered from one to eight. In the next step, each of these blocks will be randomly selected by performing lottery using 8 cards with numbers 1 to 8 on them. Thus, in each lottery, by selecting a block, a combination of 10 letters of the letters A (Famotidine/vitamin B6 group) and B (placebo group) will be obtained. At the end of the 8 drawings, after selecting 8 blocks, a total of 80 letters A and B will be obtained. The resulting combination of letters A and B is single, and will be placed in 80 separate and sealed envelopes, respectively. Following each patient recourse, an envelope will be opened to determine the group of that patient.

Blinding (investigator's opinion)
Double blinded

Blinding description
The medication and placebo are delivered to the patient without sticking the name of the medication. The doctor is also unaware of the type of drug used in each group. The color and smell of the main drug and placebo are the same.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee Kermanshah University of Medical Sciences
Street address
Vice Chancellor for Research Affairs, Building No.2, Kermanshah University of Medical Sciences, Shahid Beheshti boulevard
City
Kermanshah
Province
Kermanshah
Postal code
6719851115

Approval date
2023-01-08, 1401/10/18

Ethics committee reference number
IR.KUMS.MED.REC.1401.274

Health conditions studied

1

Description of health condition studied
Schizophrenia

ICD-10 code
F20

ICD-10 code description
Schizophrenia

Primary outcomes

1

Description
Severity of negative symptoms

Timepoint
before intervention- 6 weeks later- 12 weeks late

Method of measurement
Positive and Negative Symptom Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The group will receive the combination of famotidine/vitamin B6 pills in three months. The daily dose will be 1 pill of 190 mg (famotidine, 40 mg and vitamin B6, 150 mg). These pills will be given to patients without awareness of the patient and the examiner. Famotidine/vitamin B6 pills will be purchased from Caspin Daru Pharmaceutical Company.

Category

Treatment - Drugs

2

Description

Control group: The control group will receive placebo treatment in three months. Daily drug intake will be 1 pill of 190 mg. Placebo pills in terms of shape, size, color and smell are similar to the Famotidine/vitamin B6 pills. placebo will be purchased from Caspin Daru Pharmaceutical Company.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Farabi Hospital

Full name of responsible person

Sara Hojatitabar

Street address

Farabi Hospital; Isar square

City

Kermanshah

Province

Kermanshah

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بلوار ایثار، بیمارست

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Korosh Hamzehee

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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

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Shakiba Salmani

Position

Assistant Psychiatrist

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Fariba Kakeri

Position

Assistant Professor

Latest degree

Specialist

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Research Assistant

Latest degree

Master

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available