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 is 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
Iran (Islamic Republic of)

Phone
+98 838264513

Email address
mo.alikhani@kums.ac.ir

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
Postal code
بلوار ایثار، بیمارست
Phone
+98 83 3827 6683
Email
mdsarahojati@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Koroush Hamzehee
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
Phone
+98 83 3836 0014
Email
khamzehee@kums.ac.ir
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
Psychiatrics
Street address
Farabi Hospital; Isar square
City
Kermanshah
Province
Kermanshah
Postal code
6719851115
Phone
+98 83 3826 4513
Email
shakiba.salmani@yahoo.com

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
Other areas of specialty/work
Psychiatrics
Street address
Farabi Hospital; Isar square
City
Kermanshah
Province
Kermanshah
Postal code
6719851115
Phone
+98 83 3826 4513
Email
faribakakery@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Mostafa Alikhani
Position
Research Assistant
Latest degree
Master
Other areas of specialty/work
Psychology
Street address
Farabi Hospital; Isar square
City
Kermanshah
Province
Kermanshah
Postal code
6719851115
Phone
+98 83 3826 4513
Email
m.alikhani18@yahoo.com

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