

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Clinical trial on the effectiveness of the Famotidine on symptoms of schizophrenic patients

Protocol summary

Study aim

This study was designed to evaluate the effectiveness of the Famotidine on symptoms of schizophrenic patients as a clinical trial.

Design

Clinical trials with a control groups, parallel groups. After sampling, samples are randomly assigned to a control group and intervention group(64 patients with schizophrenia, phase 3) .

Settings and conduct

The target population of this study will be 64 hospitalized patients with schizophrenia who referred to the Shafa hospital in Rasht. Patients will be selected by a psychiatrist based on Diagnostic and Statistical Manual of Psychiatric Disorders (DSM5) clinical interviews. After obtaining informed consent, the patients will be included in the study with sampling method, observing inclusion and exclusion criteria. After sampling, samples are randomly assigned to a control group and intervention group. Individuals in intervention group receive standard Psychiatric medication (Olanzapine at a dosage of 10 to 25 mg, daily) and for 6 weeks a Famotidine. The effectiveness of the treatment will be evaluated in Baseline and Six weeks after the intervention based on the score obtained from the Wechsler Memory Scale(WMS) and Positive and Negative Symptoms of Schizophrenia(PANSS).

Participants/Inclusion and exclusion criteria

The diagnosis of schizophrenia based on Diagnostic and Statistical Manual of Psychiatric Disorders (DSM5), Patients receiving second-generation drugs

Intervention groups

Intervention group: Individuals in intervention group will receive for 6 weeks a Famotidine (40 mg, daily). Also patients will receive their standard Psychiatric medication(Olanzapine at a dosage of 10 to 25 mg, daily). Control group: Individuals in control group will receive their standard Psychiatric medication (Olanzapine at a dosage of 10 to 25 mg, daily).

Main outcome variables

symptoms of schizophrenic patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190707044123N1**

Registration date: **2019-07-15, 1398/04/24**

Registration timing: **prospective**

Last update: **2019-07-15, 1398/04/24**

Update count: **0**

Registration date

2019-07-15, 1398/04/24

Registrant information

Name

Ali Pourramzani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3366 6268

Email address

ali.pourramazani@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-16, 1398/04/25

Expected recruitment end date

2019-08-16, 1398/05/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial on the effectiveness of the Famotidine on symptoms of schizophrenic patients

Public title

Clinical trial on the effectiveness of the Famotidine on symptoms of schizophrenic patients

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

The diagnosis of schizophrenia based on Diagnostic and Statistical Manual of Psychiatric Disorders (DSM5)

Patients receiving second-generation drugs A year past diagnosis of schizophrenia Patients have a secondary school education

Exclusion criteria:

Sensitivity to famotidine Drug abuse Serious medical illness (Nephrology disease)

Age

From **25 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

After convenience sampling, Participants will be assigned to three groups of 32 people using closed envelopes with blocked randomization method. Blocking will be used to create the number of samples assigned to each treatment group. In this study, people will be divided into 16 blocks of 4. Patients with the ability to enter this clinical trial are categorized as 1 to 1 in two groups of intervention and control.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Deputy of Research and Technology University, The old building of the School of Health, in front of 17 shahrivar Hospital, Shahid Siadati St., Namjoo St.

City

Rasht

Province

Guilan

Postal code

41446-66949

Approval date

2019-06-26, 1398/04/05

Ethics committee reference number

IR.GUMS.1398.132

Health conditions studied

1

Description of health condition studied

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

Symptoms of schizophrenia

Timepoint

The effectiveness of the treatment will be evaluated in Baseline and Six weeks after the intervention.

Method of measurement

The effectiveness of the treatment will be evaluated in Baseline and Six weeks after the intervention based on the score obtained from the Wechsler Memory Scale(WMS) and Positive and Negative Symptoms of Schizophrenia(PANSS).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Individuals in intervention group will receive for 6 weeks a Famotidine (40 mg, daily). Also patients will receive their standard Psychiatric medication(Olanzapine at a dosage of 10 to 25 mg, daily).

Category

Treatment - Drugs

2

Description

Control group: Individuals in control group will receive their standard Psychiatric medication (Olanzapine at a dosage of 10 to 25 mg, daily).

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa Hospital

Full name of responsible person

Dr Ali Pourramzani

Street address

15 khordad avenue, Shafa Hospital, Rasht, Iran

City

Rasht

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Postal code

41939-55599

Phone

+98 13 3366 6268

Email

ali.pourramazani@gums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr Ali Pourramzani

Street address

15 khordad avenue, Shafa Hospital, Rasht, Iran

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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

Rasht University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Mona Mousaei

Position

Researcher staff

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr Ali Pourramzani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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41939-55599

Phone

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Email

Person responsible for updating data

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Mona Mousaei

Position

Research staff

Latest degree

Master

Other areas of specialty/work

Psychology

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Email

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only part of the data, such as the key outcome information or the like, can share.

When the data will become available and for how long

The beginning of the access period since early 2020

To whom data/document is available

It will be available to doctors and researchers working in academic and academic institutions.

Under which criteria data/document could be used

Eligible persons can send their application by e-mail to access relevant information so that they can be sent to them if they identify the project implementer.

From where data/document is obtainable

Email to head of project

What processes are involved for a request to access data/document

After the email is submitted to the head of project, the requesting person will receive the response within a few days.

Comments