

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Investigating the effect of Famotidine on cognitive and behavioral dysfunctions induced by COVID-19: A randomized double blind and placebo controlled clinical trial

Protocol summary

Study aim

The effect of Famotidine on cognitive and behavioral dysfunctions induced by COVID-19

Design

Randomized double blind and placebo-controlled clinical trial

Settings and conduct

This study will be performed on patients with COVID-19 attending Imam Khomeini Hospital in Tehran

Participants/Inclusion and exclusion criteria

Inclusion criteria: History of hospitalization due to COVID-19 - At least 20 days from the onset of symptoms, and 7 days from the last day of symptoms passed - Diagnosis of cognitive impairment (score 23 or less in MMSE test, or score 22 or less in MoCA test) - Age between 18-65. Exclusion criteria: Being psychotic - Presence of other psychiatric disorders - Using other psychiatric drugs or any drug which can affect cognitive performance - History of ECT during past 2 months - Presence of thyroid disease - Presence of kidney disease - Presence of liver disease - History of cognitive impairment or dementia - Pregnant or lactating women

Intervention groups

Intervention group: Famotidine 80 mg per day for 3 months. Control group: Placebo for 3 months.

Main outcome variables

Severity of cognitive impairments

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090117001556N138**

Registration date: **2021-08-03, 1400/05/12**

Registration timing: **prospective**

Last update: **2021-08-03, 1400/05/12**

Update count: **0**

Registration date

2021-08-03, 1400/05/12

Registrant information

Name

Shahin Akhondzadeh

Name of organization / entity

Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 2222

Email address

s.akhond@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2023-09-23, 1402/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of Famotidine on cognitive and behavioral dysfunctions induced by COVID-19: A randomized double blind and placebo controlled clinical trial

Public title

Famotidine for the improvement of cognitive impairments in COVID-19 patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

History of hospitalization due to COVID-19 At least 20 days from the onset of symptoms, and 7 days from the last day of symptoms passed Diagnosis of cognitive impairment (score 23 or less in MMSE test, or score 22 or less in MoCA test) Age between 18-65

Exclusion criteria:

Being psychotic Presence of other psychiatric disorders Using other psychiatric drugs or any drug which can affect cognitive performance History of ECT during past 2 months Presence of thyroid disease Presence of kidney disease Presence of liver disease History of cognitive impairment or dementia Pregnant or lactating women

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization: using blocks with n=4; AABB, ABAB, ABBA, BABA, BAAB, BBAA. We randomly use the blocks to achieve total sample size. ("A" and "B" are the study groups)

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants, care providers and outcome assessors will be blind regarding grouping. All the participants believe that they are taking the main medication (the participants who are taking placebo are not aware of it). Care providers and outcome assessors do not know which participants have received the main medication and which participants have received placebo. Thus, there is no orientation in their work process.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Qhods St., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2021-02-27, 1399/12/09

Ethics committee reference number

IR.TUMS.DDRI.REC.1400.019

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

Severity of cognitive impairment

Timepoint

Baseline and months 1.5 and 3

Method of measurement

by Mini mental state Exam (MMSE), Montreal Cognitive Assessment (MoCA), Hamilton Depression Rating Scale (HAM-D), Hamilton Anxiety Rating Scale (HAM-A)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Famotidine 80 mg per day for 3 months.

Category

Treatment - Drugs

2

Description

Control group: Placebo for 3 months

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Roozbeh hospital
Full name of responsible person
Prof. Mohammad Reza Mohammadi
Street address
Roozbeh Hospital, South Kargar Street
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Mohammad Ali Sahraian
Street address
Tehran University of Medical Sciences, Qhods St.,
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msahrai@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Shahin Akhondzadeh
Position
Professor of clinical psychopharmacology
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity
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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

No - There is not a plan to make this available

Title and more details about the data/document

The data will be distributed through final report

When the data will become available and for how long

5 years from 2021 to 2026

To whom data/document is available

academic researchers

Under which criteria data/document could be used

users should cite the resource of data

From where data/document is obtainable

Prof Shahin Akhondzadeh

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

by E mail

Comments