

# 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  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1333715914  
**Phone**  
+98 21 5541 2222  
**Email**  
mohammadimr@tums.ac.ir

## 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.,  
Keshavarz Blvd.  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1417653761  
**Phone**  
+98 21 8898 7381  
**Email**  
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  
**Street address**  
Roozbeh Hospital, South Kargar Street, Tehran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1333715914  
**Phone**  
+98 21 5541 2222  
**Email**  
s.akhond@sina.tums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Prof. Shahin Akhondzadeh  
**Position**  
Professor of clinical psychopharmacology  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Medical Pharmacy  
**Street address**  
Roozbeh Hospital, South Kargar Street, Tehran  
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**Email**  
s.akhond@sina.tums.ac.ir

## Person responsible for updating data

### 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

**Street address**

Roozbeh Hospital, South Kargar Street

**City**

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1333715914

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+98 21 5541 2222

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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**