Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

The effect of Famotidine on the improvement of patients with COVID-19

Protocol summary

Study aim
This study aims to investigate the effect of Famotidine on the recovery process of COVID-19 patients.

Design
Concealed, randomized, single blinded, phase 3 controlled clinical trial with two arm parallel group design of 20 patients, using the placebo in the control group.

Settings and conduct
This study will be performed in Shahid Mohammadi Hospital in Bandar Abbas city. Patients enter the study after obtaining written consent. Patients are randomly assigned to one of the intervention or control groups with the placebo. Also, patients will not know which group they belong to. (single blinded)

Participants/Inclusion and exclusion criteria
All COVID-19 patients admitted to Shahid Mohammadi Hospital in Bandar Abbas whose PCR test results are positive for SARS-Cov-2 and sign the written consent of the study are included in the study and immunocompromised patients, end-stage renal disease, moderate renal failure (clearance Creatinine 30 to 50 ml/min) or stage 4 severe chronic kidney disease or need for dialysis (creatinine clearance lesser than 30 ml/min), history of liver disease, hepatitis C infection or alcoholism, Glucose 6 phosphate dehydrogenase deficiency(G6PD), the ratio of Alanine transaminase to Aspartate transaminase 5 times above the normal limit, history or evidence of long QT segment on Electrocardiogram, psoriasis or porphyria, pregnancy, use of oral contraceptives, Dasatinib, Neratinib, Ozanimod, Pazopanib, Rilpivirine, Siponimod and/or Tizanidine and allergies to any study drug are excluded.

Intervention groups
Patients are divided into two groups. In group A, the standard treatment for COVID-19 patients with Famotidine is prescribed. In group B, patients receive standard COVID-19 treatment with the placebo.

Main outcome variables
Patient's clinical symptoms and laboratory examinations.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200509047364N2**
Registration date: **2020-08-17, 1399/05/27**
Registration timing: **registered_while_recruiting**

Last update: **2020-08-17, 1399/05/27**
Update count: **0**

Registration date
2020-08-17, 1399/05/27

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-06-21, 1399/04/01
Expected recruitment end date
2020-12-21, 1399/10/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Famotidine on the improvement of patients

with COVID-19

Public title
Famotidine and COVID-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All COVID-19 patients whose disease has been confirmed by the PCR test for SARS-Cov-2. Signing the written consent of the study participant.
Exclusion criteria:
All Immunocompromised patients End stage renal disease Moderate renal insufficiency (creatinine clearance 30-50 mL/min) stage 4 sever chronic kidney disease requiring dialysis (i.e creatinine clearance <30 mL/min) History of hepatic disease History of hepatitis C infection History of alcoholism G-6-PD (glucose-6-phosphate dehydrogenase deficiency) ALT/AST >5 times the upper limit of normal. History of or evidence of QT prolongation on ECG examination History of psoriasis History of porphyria Pregnancy Use of oral contraceptive pills (OCP) Concomitant use of Dasatinib Concomitant use of Neratinib Concomitant use of Ozanimod Concomitant use of Pazopanib Concomitant use of Rilpivirine Concomitant use of Siponimod Concomitant use of Tizanidine Allergy to any study medication
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
Before assigning groups to individuals eligible to participate in the study, informed consent is completed for grouping individuals. the person who has no role in admitting patients and assigning patients to random codes preparing random sequences using online tools (https://www.sealedenvelope.com/) and by permuted block randomization method. Individualized random allocation is done in blocks with sizes 2 and 4, and without stratification. eligibility criteria are monitored by the person responsible for admitting patients. Codes in a random sequence are assigned to patients by the treatment team without knowing that each code is in the intervention or placebo group. Patient codes are then matched to randomly generated sequence information for interventions. (randomization concealment is done by the treatment team without informing the person responsible for admitting patients and the person who prepared the random sequence.)
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, all participants are aware of participating in this study and enter the study with their consent. All participants are unaware of which group of this study they are in and after grouping patients in the groups, Patients receive Famotidine in the treatment group and receive a placebo in the control group. The lead researcher, health care personnel, data collection officials, and those who evaluate the outcome are aware of the grouping of patients. Those who prepare the draft of the article are unaware of the groupings if they do not cooperate in the above cases.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Hormozgan University of Medical Sciences
Street address
Deputy of Research and Technology, Hormozgan University of Medical Sciences, Shahid Chamran Boulevard, Bandar Abbas, Hormozgan, Iran
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Province
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Postal code
7916613885
Approval date
2020-08-02, 1399/05/12
Ethics committee reference number
IR.HUMS.REC.1399.255

Health conditions studied

1

Description of health condition studied
Laboratory confirmed COVID-19
ICD-10 code
U07.1
ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
Respiratory rate
Timepoint

At the beginning of the study (before the intervention) and day 14 after the intervention or the day of patient's discharge.

Method of measurement

Pulse oximeter

2

Description

Oxygen saturation state

Timepoint

At the beginning of the study (before the intervention) and day 14 after the intervention or the day of patient's discharge.

Method of measurement

Pulse oximeter

3

Description

Lung infiltration status

Timepoint

At the beginning of the study (before the intervention) and day 14 after the intervention or the day of patient's discharge.

Method of measurement

Chest X-ray

4

Description

Lactate Dehydrogenase(LDH) level's

Timepoint

At the beginning of the study (before the intervention) and day 14 after the intervention or the day of patient's discharge.

Method of measurement

Pathobiology laboratory

5

Description

C-reactive protein(CRP) level's

Timepoint

At the beginning of the study (before the intervention) and day 14 after the intervention or the day of patient's discharge.

Method of measurement

Pathobiology laboratory

6

Description

Lymphocyte count

Timepoint

At the beginning of the study (before the intervention) and day 14 after the intervention or the day of patient's discharge.

Method of measurement

Pathobiology laboratory

7

Description

Platelet count

Timepoint

At the beginning of the study (before the intervention) and day 14 after the intervention or the day of patient's discharge.

Method of measurement

Pathobiology laboratory

Secondary outcomes

1

Description

Patient temperature status

Timepoint

At the beginning of the study (before the intervention), days 1 to 14 of the intervention or the time of the patient's discharge.

Method of measurement

Digital thermometer

2

Description

Length of hospitalization

Timepoint

At the beginning of the study (before the intervention), days 1 to 14 of the intervention or the time of the patient's discharge.

Method of measurement

Record patient information

3

Description

Length of Intensive Care Unit admission

Timepoint

At the beginning of the study (before the intervention), days 1 to 14 of the intervention or the time of the patient's discharge.

Method of measurement

Record patient information

Intervention groups

1

Description

Intervention group: Group A receives standard pharmacotherapy according to the treatment protocols of the National Committee of COVID-19 and oral famotidine 160 mg (Manufactured by Chemidarou Pharmaceutical Company) four times a day until the day of discharge, for a maximum of fourteen days. Vital signs of patients are also checked at regular intervals and frequently. Standard pharmacotherapy according to the treatment protocols of the National Committee of COVID-19 includes Hydroxychloroquine / Chloroquine Phosphate: Hydroxychloroquine sulfate tablets 200 mg or chloroquine phosphate tablets 250 mg (equivalent to

150 mg base dose) 2 tablets every 12 hours on the first day and then one tablet every 12 hours for at least 7 days and up to 14 days. One of the following medications at the discretion and diagnosis of the treating physician: kaletra tablets (Lopinavir / Ritonavir) 50/200 mg every 12 hours 2 pieces after meals for at least 7 days and a maximum of 14 days. Tablets (Atazanavir / Ritonavir) 300/100 One tablet daily with food or Atazanavir 400 mg daily for at least 7 days and up to 14 days.

Category

Treatment - Drugs

2

Description

Control group: Group B receives standard drug therapy according to the treatment protocols of the National Committee COVID-19 and placebo in the form of oral tablets four times a day, daily until patients are discharged, for a maximum of fourteen days. Standard pharmacotherapy according to the treatment protocols of the National Committee of COVID-19 includes Hydroxychloroquine / Chloroquine Phosphate: Hydroxychloroquine sulfate tablets 200 mg or chloroquine phosphate tablets 250 mg (equivalent to 150 mg base dose) 2 tablets every 12 hours on the first day and then one tablet every 12 hours for at least 7 days and up to 14 days. One of the following medications at the discretion and diagnosis of the treating physician: kaletra tablets (Lopinavir / Ritonavir) 50/200 mg every 12 hours 2 pieces after meals for at least 7 days and a maximum of 14 days. Tablets (Atazanavir / Ritonavir) 300/100 One tablet daily with food or Atazanavir 400 mg daily for at least 7 days and up to 14 days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mohammadi Hospital

Full name of responsible person

Dr. Mehdi Hassaniazad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Dr. Teamur Aghamolaei

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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

Bandare-abbas 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

Bandare-abbas University of Medical Sciences

Full name of responsible person

Dariush Hooshyar

Position

Student of Medicine

Latest degree

Medical doctor

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