Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

: Evaluation of the effect of spironolactone and DDP4 inhibitors on treatment of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2 or COVID-19)

Protocol summary

Study aim

Determining the effect of DPP4 and spironolactone inhibitors in the treatment of COVID-19 Determining the effect of DPP4 inhibitors and spironolactone on blood oxygen saturation and Lung HRCT findings in COVID19 patients.

Design

The study will be a 4arms clinical trial with parallel groups.The three intervention groups will receive Sitagliptin , Spironolactone, and a combination of both drugs, respectively, and all intervention and control groups will receive COVID 19 standard treatment. Each group will have 50 patients whom are allocated to the groups using block randomization method.

Settings and conduct

This study will be performed in Bushehr's Shohadaye Khalije Fars Hospital. After reviewing the patient's history, examinations and paraclinical findings, the researcher will enter patients into the study and then the patients admitted to the study will be randomly allocate to each study groups. General condition, respiratory status, SPO2, CT scan report and patient paraclinical information at first, third and fifth day of the study will be included in the checklist.

Participants/Inclusion and exclusion criteria

inclusion: admitted patients in Bushehr's SKF hospital due to PCR positive COVID19 >= 20 years old exclusion: pregnancy spironolactone or DPP4 inhibitor consumption drug contraindications intubation and mechanical ventilation at admission onset

Intervention groups

All patients will receive standard treatment of Covid 19 based on the Ministry of Health guidelines (dexamethasone, antiviral treatment, antibiotic treatment, anticoagulant, supplement, etc.). In addition, the first and second intervention groups will receive 100 mg of sitagliptin and Spironolactone daily, respectively for 5 days, and the third intervention group receives both of these drugs in combination for 5 days.

Main outcome variables

blood Oxygen saturation percentage Lung HRCT findings

General information

Reason for update

To add OPD patients to our intervention in an intervention group and a control group.

Acronym

IRCT registration information

IRCT registration number: **IRCT20201003048904N2**
Registration date: **2020-12-10, 1399/09/20**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-07, 1400/11/18**
Update count: **1**

Registration date

2020-12-10, 1399/09/20

Registrant information

Name

Farhad Abbasi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 77 3355 8990

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-05, 1399/09/15

Expected recruitment end date

2021-02-18, 1399/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

: Evaluation of the effect of spironolactone and DDP4 inhibitors on treatment of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2 or COVID-19)

Public title

combination therapy trial in COVID-19 patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

admitted patients in Bushehr's Shohadaye_Khalije_Fars hospital due to COVID19 diagnosis confirmed by Rt-PCR age equal or more than 20 Male and female OPD patients with confirmed or probable SARS-CoV-2 infection according to WHO and CDC definitions referred to Motahari Clinic.

Exclusion criteria:

pregnancy positive history of spironolactone or DPP4 inhibitor consumption contraindications for drug intervention consumption (Plasma Acid/base, Electrolyte or Glucose abnormalities) hypersensitivity to drugs patient dissatisfaction intubation and mechanical ventilation at admission onset

Age

From **20 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Inpatient: Randomization will be done by Blocked Randomization method. four groups D, B, S and C are considered as intervention and control groups. 24 blocks are formed from the combination of the letters above. Considering that there are 50 patients in each group, a total of 200 samples are needed, so 9 of the above blocks are randomly selected (placing all 24 types of blocks in a container and selecting it randomly and by placement) will be written in a chain. Patients in group D will eventually receive DPP4 inhibitors, group S will receive spironolactone, group B will receive both drugs, and patients in group C will be in control group, and the client will be identified in advance. Outpatient: the intervention is performed in two separate clinics. One clinic prescribes only standard Covid treatment and one clinic provides dual drug treatment in addition to standard treatment.

Blinding (investigator's opinion)

Double blinded

Blinding description

After receiving an explanation about how to implement the plan and the nature of the drugs received, as well as the possible benefits and side effects, the patient will not know which group he is in. Also, the details of which group the results belong to will not be provided to the statistical analyzer.

Placebo

Not used

Assignment

Parallel

Other design features

Intervention in outpatients and inpatients will be done separately. In outpatients, a control group will receive standard Covid treatment. And the other group who go to another clinic will receive dual drug treatment in addition to the standard Covid treatment. The intervention in hospitalized patients is designed as four arms, which has been described before.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Bushehr university of medical sciences

Street address

Salman_farsi Blvd

City

Bushehr

Province

Boushehr

Postal code

7514633341

Approval date

2020-11-18, 1399/08/28

Ethics committee reference number

IR.BPUMS.REC.1399.140

Health conditions studied

1

Description of health condition studied

COVID19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description
The blood oxygen saturation percentage is examined as an index of oxygenation status.
Timepoint
first, third and fifth day of study
Method of measurement
pulsoxymeter

Secondary outcomes

1

Description
Lung involvement description and percentage in lung HRCT scan.
Timepoint
first and fifth day of study
Method of measurement
Lung HRCT scan which will be reported by a radiologist

Intervention groups

1

Description
Intervention group 1: will receive sitagliptin 100 mg daily for 5days in addition to standard treatment of COVID19
Category
Treatment - Drugs

2

Description
Intervention group 2: will receive spironolactone 100 mg daily for 5 days in addition to standard treatment of COVID19
Category
Treatment - Drugs

3

Description
Intervention group 3: will receive spironolactone 100 mg daily and sitagliptin 100 mg for 5 days in addition to standard treatment of COVID19
Category
Treatment - Drugs

4

Description
Control group: will receive only standard treatment of COVID19
Category
Treatment - Drugs

5

Description
Intervention group: OPD prescription of combination of spironolactone 100 mg daily and Januvia 100 mg daily in addition to standard treatment of COVID19
Category
Treatment - Drugs

6

Description
Control group: OPD prescription of standard treatment for COVID-19
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Bushehr's Shohadaye Khalije Fars Hospital
Full name of responsible person
Farhad Abbasi
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Recruitment center
Name of recruitment center
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Name of recruitment center

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Sponsors / Funding sources

1

Sponsor
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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
Boushehr 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
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Position
assistant professor
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MD, Non-faculty member
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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

The main variables and outcomes studied will be published: Percentage of blood oxygen saturation, CT scan, and demographic variables

When the data will become available and for how long

12 months after publishing the results

To whom data/document is available

faculty members

Under which criteria data/document could be used

To integrate data with other studies

From where data/document is obtainable

Dr Farhad Abbasi: f_abbasi55@yahoo.com

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

The objectives and scope of the draft research plan are reviewed and approved if they are consistent with the data.

Comments