

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Evaluation the efficacy and safety of Sitagliptin administration in patients with COVID-19

Protocol summary

Study aim

Evaluation the efficacy and safety of Sitagliptin administration in patients with COVID-19

Design

Randomized clinical trial with control group, Clinical Trial 3, Sample size: 84

Settings and conduct

This study will be performed as a randomized clinical trial with a control group and sample size of 84 in Dr. Masih Daneshvari Hospital. In this study, patients in Sitagliptin group receive Sitagliptin (Dr.Abidi Pharmaceuticals, Iran) at dose of 50 mg BID twice a day for totally 10 days and the control group will not take this medicine. The other standard and supportive treatment will be done (including Lopinavir and ritonavir at dose of 200/50 mg two tablets BID Hydroxychloroquine sulfate 400 mg one dose) for both groups similarly.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Laboratory confirmed COVID-19 with RT-PCR, Age over 18 years old, Oxygen saturation < 93%, Fever more than 72 hours before admission, Bilateral pulmonary infiltration Exclusion criteria: Chronic kidney Disease, Acute kidney Injury, Pregnancy or breastfeeding, Drug allergy, history Chronic liver disease, Mild phase of COVID-19 Critical phase of COVID-19 and Pancreatitis

Intervention groups

In this study, patients in Sitagliptin group receive Sitagliptin (Dr.Abidi Pharmaceuticals, Iran) at dose of 50 mg BID twice a day for totally 10 days and the control group will not take this medicine. The other standard and supportive treatment will be done (including Lopinavir and ritonavir at dose of 200/50 mg two tablets BID Hydroxychloroquine sulfate 400 mg one dose) for both groups similarly.

Main outcome variables

Fever, cough, and shortness of breath

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200420047147N1**

Registration date: **2020-04-23, 1399/02/04**

Registration timing: **prospective**

Last update: **2020-04-23, 1399/02/04**

Update count: **0**

Registration date

2020-04-23, 1399/02/04

Registrant information

Name

Ahad Zare

Name of organization / entity

Department of Immunology, Faculty of Medicine, Tehran Medical Sciences, Islamic Azad University, Tehr

Country

Iran (Islamic Republic of)

Phone

+98 21 4467 0888

Email address

ahadzaree@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-04, 1399/02/15

Expected recruitment end date

2020-08-05, 1399/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the efficacy and safety of Sitagliptin administration in patients with COVID-19

Public title

Evaluation the effects of Sitagliptin administration in patients with COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who diagnosed with COVID-19 by RT-PCR test
Oxygen saturation less than 93% Age more than 18 years old To sign the informed consent form

Exclusion criteria:

Chronic kidney disease Acute kidney injury Chronic liver disease pregnancy or breastfeeding Pancreatitis Allergy to Sitagliptin Pemphigus disease history

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization method was used in this study. 21 blocks including 4 patients generated with online website (www.randomizer.org). In each block, two patients will be assigned to Sitagliptin group and two patients will be assigned to Control group by random order.

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

National Research Institute of Tuberculosis and Lung Diseases - Shahid Beheshti University of Medica

Street address

Darabad Avenue, Shahid Bahonar roundabout, Niavaran, Masih Daneshvari Hospital

City

Tehran

Province

Tehran

Postal code

1956944413

Approval date

2020-04-07, 1399/01/19

Ethics committee reference number

IR.SBMU.NRITLD.REC.1399.029

Health conditions studied

1

Description of health condition studied

Pneumonia of COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

Fever

Timepoint

Daily, From admission to discharge time

Method of measurement

Thermometer

2

Description

Cough

Timepoint

Daily, From admission to discharge time

Method of measurement

Observation

3

Description

Dyspnea

Timepoint

Daily, From admission to discharge time

Method of measurement

Observation

Secondary outcomes

1

Description

Hospitalization duration

Timepoint

At admission time and discharge time

Method of measurement

Clinical records

2

Description

Lung radiology changes

Timepoint

At admission time and 14 days later

Method of measurement

Computed tomography

3

Description

Adverse Drug Reaction

Timepoint

Daily, From admission to discharge time

Method of measurement

Observation

4

Description

Virological clearance

Timepoint

At admission time and 14 days later

Method of measurement

Reverse transcription polymerase chain reaction

5

Description

Needs to mechanical ventilation

Timepoint

Daily, From admission to discharge time

Method of measurement

Medical Record

6

Description

Death

Timepoint

At end of the study

Method of measurement

Medical Record

Intervention groups

1

Description

Intervention group: Patients in Sitagliptin group receive Sitagliptin (Dr. Abidi Pharmaceuticals, Iran) at dose of 50 mg BID twice a day for totally 10 days and the other standard and supportive treatment (including Lopinavir and ritonavir at dose of 200/50 mg two tablets BID and Hydroxychloroquine sulfate 400 mg one dose) will be administered.

Category

Treatment - Drugs

2

Description

Standard and supportive treatment (including Lopinavir and ritonavir at dose of 200/50 mg two tablets BID and Hydroxychloroquine sulfate 400 mg one dose) will be administered.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Masih Daneshvari Hospital

Full name of responsible person

Dr. Atefe Abedini

Street address

Masih Daneshvari Hospital, Darabad Avenue, Tehran, Iran

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Phone

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Email

dr.abedini110@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

3rd floor, School of Medicine, Evin St, Shahid Chamran Highway

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1983963113

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mpd@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

80

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

2

Sponsor

Name of organization / entity
Sarem Cell Research Center (SCRC), Sarem Women's Hospital, Tehran, Iran
Full name of responsible person
Ahad Zare
Street address
Sarem Hospital, Ekbatan town
City
Tehran
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1396956111
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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

Sarem Cell Research Center (SCRC), Sarem Women's Hospital, Tehran, Iran

Proportion provided by this source

20

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

Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Farzaneh Dastan
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Sarem Cell Research Center(SCRC), Sarem Women's Hospital.

Full name of responsible person

Ahad Zare

Position

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Latest degree

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Other areas of specialty/work

Immunology

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Atefeh Abedini

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Interventional Pulmonology

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Fax**Email**

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

All potential data can be shared after blinding

When the data will become available and for how long

Six months after publishing

To whom data/document is available

Researchers

Under which criteria data/document could be used

For research purposes and meta-analysis studies

From where data/document is obtainable

Dr. Ahad Zare/ Sarem Women's Hospital, Ekbatan Town, Tehran, Iran
Dr. Farzaneh Dastan, Dr. Atefeh Abedini/
Masih Daneshvari Hospital, Darabad Avenue, Shahid Bahonar roundabout, Tehran, Iran.

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

Official letter to the researchers

Comments