

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Feb 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](http://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

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1956944413

##### **Phone**

+98 21 2610 5050

##### **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

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1983963113

##### **Phone**

+98 21 23871

##### **Email**

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  
**Province**  
Tehran  
**Postal code**  
1396956111  
**Phone**  
+98 21 4467 0888  
**Email**  
ahadzareee@gmail.com

### **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

### **Street address**

Masih Daneshvari Hospital, Darabad Avenue, Tehran, Iran

### **City**

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### **Province**

Tehran

### **Postal code**

1956944413

### **Phone**

+98 21 2610 5050

### **Email**

fzh.dastan@gmail.com

## **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**

Assistant Professor

#### **Latest degree**

Ph.D.

#### **Other areas of specialty/work**

Immunology

#### **Street address**

Sarem Women's Hospital, Ekbatan Town, Tehran, Iran

#### **City**

Tehran

#### **Province**

Tehran

#### **Postal code**

139656111

#### **Phone**

+98 21 4467 0888

#### **Email**

ahadzareee@gmail.com

## **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

#### **Street address**

Masih Daneshvari Hospital, Darabad Avenue, Tehran, Iran

#### **City**

Tehran

#### **Province**

Tehran

**Postal code**

1956944413

**Phone**

+98 21 2610 5050

**Fax****Email**

dr.abedini110@gmail.com

## 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**