Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 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
ahadzareee@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
City
Tehran
Province
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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
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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

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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

Assistant Professor

Latest degree

Ph.D.

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

Street address

Masih Daneshvari Hospital, Darabad Avenue, Tehran, Iran

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Fax
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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 mounts 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