Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Study of the effect of dipeptidyl peptidase 4 inhibitors on the improvement rate and prognosis of diabetic patients with Covid-19

Protocol summary

Study aim
Determining the effect of dipeptidyl peptidase 4 inhibitors in the control and recovery of diabetic patients with SARS-COV2

Design
Randomized clinical trial with control group , sample size: 35 patients and 35 controls

Settings and conduct
This study will be performed as a double-blind, randomized clinical trial with a control group with a sample size of 70 in Golestan Hospital. Patients in the intervention group are given 100 mg of sitagliptin daily (50 mg every 12 hours). sitagliptin tablets at a dose of 50 mg twice a day will be prescribed to the sitagliptin group and the control group will not receive this drug.Standard and supportive treatment will be performed according to the national guidelines of Corona in both groups

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients who have been diagnosed with Covid 19 based on CT scan or PCR. Patients with fasting blood sugar above 100 at the time of referral, patients with previous diagnosis of diabetes and under treatment Study and accept consent to participate in the study Patients over 18 years of age Exclusion criteria: acute renal failure, chronic renal failure with stage 4,5 Acute and chronic liver failure History of immunodeficiency diseases, use of immunodeficiency drugs Pregnancy and breastfeeding Patients who are admitted to the intensive care unit upon arrival Patients with contraindications to sitagliptin (pancreatitis and its history, diabetic gastroparesis, history of hypersensitivity to the drug)

Intervention groups
Patients in the intervention group were given 100 mg of sitagliptin daily (50 mg 30<GFR <60 , 50 mg daily) and is compared with the control group in terms of clinical, vital and laboratory criteria.

Main outcome variables
fever, 02 saturation, dyspnea

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200420047147N2**
Registration date: **2022-03-07, 1400/12/16**
Registration timing: **prospective**

Last update: **2022-03-07, 1400/12/16**
Update count: **0**

Registration date
2022-03-07, 1400/12/16

Registrant information

Name
Ahad Zare

Name of organization / entity
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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-03-11, 1400/12/20

Expected recruitment end date
2022-04-19, 1401/01/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Study of the effect of dipeptidyl peptidase 4 inhibitors on the improvement rate and prognosis of diabetic patients with Covid-19

Public title
Study of therapeutic effect of sitagliptin
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who have been diagnosed with Covid 19 based on CT scan or PCR. Patients with fasting blood sugar above 100 at the time of referral Patients with previous diagnosis of diabetes and under treatment Study and accept consent to participate in the study Patients over 18 years of age
Exclusion criteria:
Acute renal failure, chronic renal failure with stage 4,5 Acute and chronic liver failure History of immunodeficiency diseases, using immunodeficiency drugs Pregnancy and breastfeeding Patients who are admitted to the intensive care unit upon arrival Patients with contraindications to cytagliptin (pancreatitis and its history, diabetic gastroparesis, history of severe drug allergy)
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization method was used in this study. 7blocks including 6 patients and 7 blocks containing 4 patients generated with online website (www.randomizer.org). In each block, half of patients will be assigned to Sitagliptin group and half of 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
Ethics committee of Aja University of Medical Sciences
Street address
West Fatemi St., Shahid Etemadzadeh St., Aja University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1411718541
Approval date
2021-01-06, 1399/10/17
Ethics committee reference number
IR.AJAUMS.REC.1399.200

Health conditions studied

1

Description of health condition studied
COVID-19
ICD-10 code
u07.1
ICD-10 code description
COVID-19 ,virus identified

Primary outcomes

1

Description
o2 saturation without mask
Timepoint
Daily
Method of measurement
Thermometer

2

Description
Fasting blood suger
Timepoint
Daily, From admission to discharge time
Method of measurement
Glucometer

3

Description
Covid-19 infection
Timepoint
At the beginning of the hospital admission
Method of measurement
Covid RT-PCR test

4

Description

Disease severity

Timepoint

At the beginning and end of intervention

Method of measurement

Based on protocol and clinical symptoms

5

Description

cbc diff

Timepoint

every other day in between from the beginning of hospitalization until discharge

Method of measurement

labratory

Secondary outcomes

1

Description

Hospitalization duration

Timepoint

discharge time

Method of measurement

clinical record

2

Description

death

Timepoint

at the end of study

Method of measurement

medical record

Intervention groups

1

Description

Intervention group: Diabetic patients with Covid-19 will be given 100 mg of sitgliptin (50 mg every 12 hours, Dr. Abidi Pharmaceuticals, Iran) daily in addition to the medications used to treat Covid 19(approved by the National Committee).and in case of chronic renal failure in stage III & IV ,25 mg every 12 hours .

Category

Treatment - Drugs

2

Description

Control group: Standard and supportive treatment will be prescribed for patients according to the Corona National Committee guidelines (glucocorticoids ± Remdesivir ± tocilizumab) will be administered

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

Mohammad Sadidi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

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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

Artesh 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
Artesh University of Medical Sciences

Full name of responsible person
Mohammad Sadidi

Position
Student

Latest degree
Specialist

Other areas of specialty/work
Internal Medicine

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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
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

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
eight mounths after publishing

To whom data/document is available
researcher

Under which criteria data/document could be used
For research purposes and meta-analysis studies

From where data/document is obtainable
mohammad sadidi AJA university of medical science

What processes are involved for a request to access data/document
Official letter to the researchers

Comments