

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, O2 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

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

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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 sitgriptin (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

Street address

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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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Person responsible for scientific inquiries

Contact

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Islamic Azad University

Full name of responsible person

Ahad Zare

Position

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Latest degree

Ph.D.

Other areas of specialty/work

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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