

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Aug 2026

Evaluation of the effect of Linagliptin on the outcome of COVID-19 in hospitalized patient with Diabetes

Protocol summary

Study aim

Evaluation the effect of Linagliptin on the outcome of COVID-19 in diabetic patients admitted to hospital

Design

Clinical trial, control group, with two arm parallel group, randomized, phase 3 on 70 patients

Settings and conduct

This clinical trial study will be performed on 70 patients with definite diagnosis of COVID-19 with PCR, hospitalized in Allameh Boohlol Gonabadi Hospital. Patients will randomly divided into two groups of 35 control and the group receiving Linagliptin. Then the outcomes will be evaluated and recorded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Consent to participate in research, Diabetes, Patients admitted to the ward with definite diagnosis of COVID-19 with PCR, Disease severity of mild to moderate. Exclusion criteria: Lack of interest to cooperate in research, History of allergies to Linagliptin, Taking interactive drugs at simultaneous use with linagliptin, according to FDA definition, Adverse drug reactions occurrence.

Intervention groups

Intervention group: (35 persons) patient will receive Tab Linagliptin 5mg (known as Melijent) once a day for 14 days in addition to standard treatment of COVID-19 based on latest national protocol. Control group: (35 person) patient will only receive standard treatment of COVID-19 based on latest national protocol.

Main outcome variables

Peripheral capillary oxygen saturation, Requirement of non-mechanical ventilation, Requirement of mechanical ventilation, Hospitalization duration, Requirement of ICU, Mortality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210812052156N1**

Registration date: **2021-10-27, 1400/08/05**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-27, 1400/08/05**

Update count: **0**

Registration date

2021-10-27, 1400/08/05

Registrant information

Name

Nahid Kheirabady

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5723 6833

Email address

nahid.khey00@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-12, 1400/07/20

Expected recruitment end date

2022-10-12, 1401/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Linagliptin on the outcome of COVID-19 in hospitalized patient with Diabetes

Public title

Effect of Linagliptin on Diabetic patients with COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Consent to participate in research Diabetes Patients admitted to the ward with definite diagnosis of COVID-19 with PCR Disease severity of mild to moderate

Exclusion criteria:

Lack of interest to cooperate in research History of allergies to Linagliptin Taking interactive drugs at simultaneous use with linagliptin, according to FDA definition Adverse drug reactions occurrence

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

In this research, patients will be randomly in one of the two groups of control or intervention by the permuted block method. The Block Sizes will be 4.

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 Gonabad University of Medical Sciences

Street address

Gonabad University of Medical Sciences, Sento Blv

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Approval date

2021-10-12, 1400/07/20

Ethics committee reference number

IR.GMU.REC.1400.083

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

Peripheral capillary oxygen saturation

Timepoint

From the beginning of admission to the hospital and daily during admission

Method of measurement

Pulse oximeter

2

Description

Requirement of non-mechanical ventilation

Timepoint

From the beginning of admission to the hospital and discharge time

Method of measurement

Patient's file in hospital

3

Description

Requirement of mechanical ventilation

Timepoint

From the beginning of admission to the hospital and discharge time

Method of measurement

Patient's file in hospital

4

Description

Hospitalization duration

Timepoint

From the beginning of admission to the hospital and discharge time

Method of measurement

Patient's file in hospital

5

Description

Requirement of ICU

Timepoint

From the beginning of admission to the hospital and discharge time

Method of measurement

Patient's file in hospital

6

Description

Mortality

Timepoint

At the end of study

Method of measurement

Patient's file in hospital

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:After reviewing the criteria for entering the study and filling the consent form, patient will receive Tab Linagliptin 5mg(known as Melijent) once a day for 14 days in addition to standard treatment of COVID-19 based on latest national protocol.

Category

Treatment - Drugs

2

Description

Control group: After reviewing the criteria for entering the study and filling the consent form, patient will only receive standard treatment of COVID-19 based on latest national protocol.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Allameh Boohlol Gonabadi Hospital

Full name of responsible person

Nahid Kheirabady

Street address

Vahdat Blvd.,Saadi St.

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Razavi Khorasan

Postal code

9691797852

Phone

+98 51 5723 6833

Email

Nahid.khey00@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Dr.Shahla Khosravan

Street address

Gonabad University of Medical Sciences, Setno Blv

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gonabad

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Nahid.khey00@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

Nahid Kheirabady

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Allameh Bohlool Gonabadi Hospital, Vahdat Blvd.,Saadi St.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Behzad Razavi

Position

Consultant, Specialist

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data

Contact

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Nahid Kheirabady

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after patients are made unidentifiable.

When the data will become available and for how long

6 months after results are published.

To whom data/document is available

Researchers in universities and other scientific institutes.

Under which criteria data/document could be used

Be useful for the treatment of patients and research purposes.

From where data/document is obtainable

Email to nahid.khey00@gmail.com.

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

After sending an emails and mentioning the required files and the cause of the demand, the requested information will be sent within a month.

Comments