Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 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 persond) 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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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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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
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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
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Other areas of specialty/work
Internal Medicine

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Person responsible for updating data

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Name of organization / entity
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Full name of responsible person
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Position
Medical Student

Latest degree
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General Practitioner

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Fax

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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