

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 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.

##### City

Gonabad

##### Province

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

##### City

gonabad

##### Province

Razavi Khorasan

##### Postal code

9691793718

##### Phone

+98 51 5722 3028

##### Email

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.

##### City

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##### Province

Razavi Khorasan

##### Postal code

9691797852

##### Phone

+98 51 5723 6833

##### Email

Nahid.khey00@gmail.com

## 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

**Street address**

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**Email**

Behzadrazavi25@yahoo.com

## 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

**Street address**

Allameh Bohlool Gonabadi Hospital, Vahdat Blvd, Saadi Ave

**City**

Gonabad

**Province**

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**Postal code**

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**Phone**

+98 51 5722 3028

**Fax**

**Email**

Nahid.khey00@gmail.com

## 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**