

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Effect of metformin in COVID-19 mortality rate and symptom improvement

Protocol summary

Study aim

Effect of meformin in hospitalization period, ARDS symptoms and mortality in patients with COVID-19

Design

The randomized clinical trial, parallel groups, 200 patients will be enrolled between 20 March 2020 till 18 April 2020

Settings and conduct

This study will be performed in emam reza hospital, Tabriz, Iran. In this study 200 patients selected based on inclusion and exclusion criteria will be divided into two groups (100 in each group) by simple randomization. Patients in control group will be prescribed standard regimen for COVID-19. Patients in Metformin group will be prescribed Metformin 500 mg BID for two weeks and standard regimen for COVID-19. The routine lab data, hospitalization period, need to intubation and mortality rate will be assessed in both groups.

Participants/Inclusion and exclusion criteria

All patients with Covid-19 symptoms in patients with a history of close contact with suspected people in the last 14 days, fever, pulmonary involvement, normal or reduced cbc, reduced lymphocyte, positive PCR involved in this study. patients with type I diabetes, Ketoacidosis, decompensated heart failure, severe kidney failure (GFR<30 ml/min), metabolic acidosis, severe respiratory failure, immediate need for intubation will exclude from the study.

Intervention groups

Control group: will receive standard regimen for COVID-19. Metformin group: will receive standard regimen for COVID-19 plus metformin 500 BID.

Main outcome variables

decrease hospitalization period; decrease ARDS symptoms; decrease mortality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160310026998N11**

Registration date: **2020-03-27, 1399/01/08**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-27, 1399/01/08**

Update count: **0**

Registration date

2020-03-27, 1399/01/08

Registrant information

Name

Saba Ghaffary

Name of organization / entity

Faculty of Pharmacy, Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 33266042

Email address

ghaffarys@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-20, 1399/01/01

Expected recruitment end date

2020-04-18, 1399/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of metformin in COVID-19 mortality rate and symptom improvement

Public title

Effect of metformin in COVID-19 symptom improvement and death

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients with Covid-19 symptoms in patients with the history of close contact with suspected people in the last 14 days fever pulmonary involvement normal or reduced cbc reduced lymphocyte, positive PCR

Exclusion criteria:

patients with type I diabetes Ketoacidosis decompensated heart failure severe kidney failure (GFR<30 ml/min) metabolic acidosis severe respiratory failure immediate need for intubation

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization generated with computer from 1 to 200. Computer will divide digits between two groups. According to the sequences of admission they will go to control or metformin group regarding computerized random list.

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 at Tabriz University of Medical Sciences

Street address

Shahid Ghazi hospital, Tabriz University of Medical Sciences, Daneshgah street

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Approval date

2020-03-16, 1398/12/26

Ethics committee reference number

IR.TBZMED.REC.1398.1310

Health conditions studied**1****Description of health condition studied**

corona virus or COVID-19

ICD-10 code

B34.2

ICD-10 code description

Coronavirus infection, unspecified

Primary outcomes**1****Description**

decreased hospitalization period

Timepoint

at baseline and discharge time

Method of measurement

counting the day

2**Description**

mortality rate

Timepoint

at baseline and discharge time

Method of measurement

observation

3**Description**

decreased need for intubation

Timepoint

at baseline and discharge time

Method of measurement

observation

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: in addition to standard regimen of covid-19 patients will be administered Metformin 500 mg

BID orally for 2 weeks.

Category
Treatment - Drugs

2

Description
Control group: standard regimen of covid-19 patients

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam Reza hospital

Full name of responsible person
Saba Ghaffary

Street address
Emam Reza hospital, Golgasht boulevard, Azadi street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz 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

Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Saba Ghaffary

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

Not applicable