Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 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
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+98 33266042
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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