Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Study of the metformin effect on the survival and recovery rate of COVID-19 patients

Protocol summary

Study aim
effect of meformin in any need to hospitalization, ARDS symptoms and mortality in patients with COVID-19

Design
The randomized clinical trial with a parallel group design in which 200 patients will be enrolled between 20 March 2020 till 18 April 2020

Settings and conduct
This study will be performed in outpatient clinic of corona of tabriz university of medical sciences,Tabriz, Iran. In this study 200 patients who are selected based on inclusion and exclusion criteria will be divided into two groups (100 in each group) by block 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, need for hospitalization and mortality rate will be assessed in both groups.

Participants/Inclusion and exclusion 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

Intervention groups
control group: received standard regimen for COVID-19 metformin group: received standard regimen for COVID-19 plus metformin 500 BID

Main outcome variables
decrease need to hospitalization; decrease ARDS symptoms; decrease mortality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160310026998N10**
Registration date: **2020-03-26, 1399/01/07**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-26, 1399/01/07**
Update count: **0**

Registration date
2020-03-26, 1399/01/07

Registrant information

Name
Saba Ghaffary

Name of organization / entity
Faculty of Pharmacy, Tabriz University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 33266042

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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
Study of the metformin effect on the survival and

recovery rate of COVID-19 patients

Public title
Study of the metformin effect on the survival and recovery rate of patients with COVID-19
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 rebal failure (GFR<30 ml/min) metabolic acidosis immediate need for intubation severe respiratory failure
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 with computer generated digits
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
Faculty pf pharmacy, Tabriz University of Medical Sciences, Shahid ghazi hospital
City
Tabriz
Province
East Azarbaijan
Postal code
5166616471
Approval date
2020-03-16, 1398/12/26
Ethics committee reference number
IR.TBZMED.REC.1398.1309

Health conditions studied

1

Description of health condition studied
corona virus
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
decreased need to hospitalization
Timepoint
2 weeks
Method of measurement
obsevation

2

Description
decreased mortality
Timepoint
2 weeks
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

Sheykhoraeis clinic
Full name of responsible person
saba ghaffary
Street address
sheikhoraeis clinic, Azadi street
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Tabriz
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51665158
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Street address
Central building of Tabriz University of Medical Sciences, Golgasht boulevard, Azadi street
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ghaffarys@tbzmed.ac.ir
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
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Position
assistant professor
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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
Undecided - It is not yet known if there will be a plan to make this available