# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 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
**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

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

51665158

**Phone**

+98 41 3336 5010

**Email**

ghaffarys@tbzmed.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Saba Ghaffary

**Street address**

Central building of Tabriz University of Medical Sciences, Golgasht boulevard, Azadi street

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

51665158

**Phone**

+98 41 3336 5010

**Email**

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**

Saba Ghaffary

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

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

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

14766 - 51664

**Phone**

+41 33365010

**Email**

ghaffarys@tbzmed.ac.ir

## Person responsible for scientific 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.

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**Email**
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## Person responsible for updating data

**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

**Street address**
Department of Pharmacotherapy, Faculty of Pharmacy, Tabriz University of Medical Sciences, Tabriz, I

**City**
Tabriz

**Province**
East Azarbaijan

**Postal code**
14766 - 51664

**Phone**
+98 33266042

**Fax**

**Email**
ghaffarys@tbzmed.ac.ir

## 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