

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

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

#### Protocol summary

##### Study aim

Effect of metformin 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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Tabriz

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**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

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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

**Street address**

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

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**Person responsible for scientific 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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Ph.D.

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant professor

**Latest degree**

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**City**

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**Province**

East Azarbaijan

**Postal code**

## 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