

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Feb 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)

##### 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

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 renal 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 of 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

observation

### 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  
**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**  
**Street address**  
Central building of Tabriz University of Medical Sciences, Golgasht boulevard, Azadi street  
**City**  
tabriz  
**Province**  
East Azarbaijan  
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51665158  
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+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  
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Department of Pharmacotherapy, Faculty of Pharmacy, Tabriz University of Medical Sciences, Tabriz, I  
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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  
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**Email**  
ghaffarys@tbzmed.ac.ir

## Person responsible for updating data

#### Contact

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**Full name of responsible person**  
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assistant professor

**Latest degree**

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**Province**

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**Postal code**

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**Phone**

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**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**

Undecided - It is not yet known if there will be a plan to make this available