

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 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
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
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

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.
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

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

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