

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Aug 2026

Evaluation of the effects of Losartan in patients with corona virus disease 2019

Protocol summary

Study aim

To evaluate the safety and efficacy of losartan in COVID-19

Design

One-hundred patients with COVID-19 after taking informed consent including 50 patients in the case group and 50 patients in the control group will be conducted parallel in the trial.

Settings and conduct

This clinical trial study will be performed in Tabriz Emam Reza hospital on patients with coronavirus disease 2019 (COVID-19). Losartan (25mg/BID) in one group and amlodipine (5mg/daily) in another group will be administered for 14 days. Also, all patients will receive routine treatment protocol of COVID-19. Lab tests and clinical features will be obtained and documented and in the end, by using the computer software (SPSS Version 24) the data will be analyzed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: laboratory (RT-PCR) confirmed COVID-19, stable hemodynamic condition, blood pressure $\geq 130/85$ mmHg. Exclusion criteria: patient's critical condition, cough exacerbation after initiating losartan, increasing blood potassium levels or high baseline potassium levels, new anemia, shock or decreasing blood pressure $\leq 90/60$ mmHg after losartan initiating, angioedema, acute hepatic failure, acute renal failure, bilateral renal artery stenosis, bilateral renal artery stenosis, history of uncontrolled hypertension, pregnancy and lactation, history of treatment with ACE inhibitors and ARB inhibitors, treatment with phenobarbital, rifampin and fluconazole

Intervention groups

In the case group, patients will receive 25 mg losartan tablets two times daily and in the control group, patients will receive 5 mg amlodipine daily.

Main outcome variables

28 days mortality, length of hospitalization, changes of laboratory and clinical findings, the performance of

patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180802040678N4**

Registration date: **2020-04-01, 1399/01/13**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-01, 1399/01/13**

Update count: **0**

Registration date

2020-04-01, 1399/01/13

Registrant information

Name

Masoud Nouri-Vaskeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3325 9778

Email address

mnvaskeh@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-31, 1399/01/12

Expected recruitment end date

2020-04-30, 1399/02/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the effects of Losartan in patients with corona virus disease 2019

Public title
Evaluation of the effects of Losartan in patients with corona virus disease 2019

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Laboratory (RT-PCR of oropharyngeal swab) confirmed COVID-19 Stable hemodynamic condition Blood pressure $\geq 130/85$ mmHg
Exclusion criteria:
 Patient's critical condition Cough exacerbation after initiating Losartan Increasing blood potassium levels or high baseline potassium levels New anemia Shock or decreasing blood pressure $\leq 90/60$ mmHg after Losartan initiating Angioedema Acute hepatic failure Acute renal failure Bilateral renal artery stenosis History of uncontrolled hypertension Pregnancy and lactation History of treatment with ACE inhibitors and ARB inhibitors Treatment with phenobarbital, rifampin and fluconazole

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomizing by computer software

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 of Tabriz University of Medical Sciences

Street address
Golgasht Ave.
City
Tabriz
Province
West Azarbaijan
Postal code
5166/15731
Approval date
2020-03-16, 1398/12/26
Ethics committee reference number
IR.TBZMED.REC.1399.002

Health conditions studied

1

Description of health condition studied
Corona virus disease 2019 (COVID-19)
ICD-10 code
B34.2
ICD-10 code description
Coronavirus infection, unspecified

Primary outcomes

1

Description
Mortality
Timepoint
28 days
Method of measurement
Number of death

2

Description
Performance of patients
Timepoint
Primary and 14 days after
Method of measurement
Sequential Organ Failure Assessment (SOFA) Respiratory Score

3

Description
Length of hospitalization
Timepoint
28 days
Method of measurement
Days between admission to discharge

4

Description
Laboratory Findings
Timepoint
Primary and 14 days after
Method of measurement
Laboratory methods

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the case group, patients will receive 25 mg losartan tablets two times daily.

Category

Treatment - Drugs

2

Description

Intervention group: Patients will receive 5 mg amlodipine daily.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Emam Reza Hospital

Full name of responsible person

Akbar Sharifi

Street address

Golgasht Ave.

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West Azarbaijan

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Phone

+98 41 3337 3966

Email

ak.sharif1349@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Samiei

Street address

Golgasht Ave.

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research-vice@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

Armin Sadeghi

Position

Clinical Fellow

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information about the study is available upon approval by the University's Ethics Committee.

When the data will become available and for how long

Starting access 6 months after publication of data

To whom data/document is available

Everybody

Under which criteria data/document could be used

Using is not authorized

From where data/document is obtainable

Applicants must send their request to the author

What processes are involved for a request to access data/document

Sending the request via e-mail

Comments

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Masoud Nouri-Vaskeh
Position
Researcher
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
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