

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 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.

#### City

Tabriz

#### Province

West Azarbaijan

#### Postal code

5166/15731

#### 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.

#### City

Tabriz

#### Province

West Azarbaijan

#### Postal code

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#### Phone

+98 41 3335 7310

#### Email

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

#### Street address

Golgasht Ave.

#### City

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#### Province

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#### Phone

+98 41 3335 7311

#### Email

arm.sad@gmail.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tabriz University of Medical Sciences

#### Full name of responsible person

Akbar Sharifi

#### Position

Associate Professor

#### Latest degree

Subspecialist

#### Other areas of specialty/work

Internal Medicine

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**Email**

mnvaskeh@tbzmed.ac.ir

**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

**Street address**

Golgasht Ave.

**City**

Tabriz

**Province**

West Azarbaijan

**Postal code**

5166/15731

**Phone**