

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Clinical Trial of renin-angiotensin-aldosterone system inhibitors with halting their administration and the effect on clinical outcomes of patients with coronavirus disease-2019 (COVID-19) referring to Sina and Imam-Khomeini Hospitals in 2020

Protocol summary

Study aim

The comparison of the clinical outcomes of patients with COVID -19 consuming renin-angiotensin-aldosterone system inhibitors with ceasing their consumption for whom calcium channel blockers with or without beta-blockers are prescribed according to the blood pressure and medication dosage.

Design

A randomized triple-blind clinical trial with parallel groups

Settings and conduct

The randomized clinical trial study will be performed in Sina and Imam-Khomeini Hospitals with triple-blinding of data recruiter, patients, and the data analyzer

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who have suggestive signs of COVID-19 in their chest computed tomography scan, reported by a radiologist. Patients consuming angiotensin-converting enzyme inhibitors or angiotensin receptor blockers Exclusion criteria: Uncontrolled hypertension with systolic blood pressure more than 180 or diastolic more than 120; past history of congestive heart failure or arrhythmia with various severity; sensitivity to the newly prescribed medications; a history of severe asthma; a history of known depression; consuming medications with interactions such as lithium, antiepileptic drugs, chemotherapy; pregnancy; patient unwillingness to enter the study; patients whose prognosis is influenced by another disease

Intervention groups

1) Patients continuing to consume medications inhibiting renin-angiotensin-aldosterone system 2) Patients whose medication inhibiting renin-angiotensin-aldosterone system is discontinued and substituted by a calcium channel blocker with or without a beta blocker

Main outcome variables

Death; ICU admission

General information

Reason for update

To add Imam-Khomeini Hospital in conducting the study

Acronym

corona virus disease-2019 (COVID-19)

IRCT registration information

IRCT registration number: **IRCT20151113025025N3**

Registration date: **2020-03-29, 1399/01/10**

Registration timing: **prospective**

Last update: **2020-07-06, 1399/04/16**

Update count: **1**

Registration date

2020-03-29, 1399/01/10

Registrant information

Name

Maryam Bahreini

Name of organization / entity

Tehran University of Medical Sciences, Sina Hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 6312 1413

Email address

m-bahreini@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-05, 1399/01/17

Expected recruitment end date

2020-09-21, 1399/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Clinical Trial of renin-angiotensin-aldosterone system inhibitors with halting their administration and the effect on clinical outcomes of patients with coronavirus disease-2019 (COVID-19) referring to Sina and Imam-Khomeini Hospitals in 2020

Public title
Clinical Trial of renin-angiotensin-aldosterone system inhibitors with halting their administration and the effect on clinical outcomes of patients with coronavirus disease-2019 (COVID-19) referring to Sina and Imam-Khomeini Hospitals in 2020

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients who have suggestive signs of COVID-19 in their chest computed tomography scan, reported by a radiologist Patients consuming angiotensin converting enzyme-inhibitors or angiotensin receptor blocker
Exclusion criteria:
 Uncontrolled hypertension with systolic blood pressure more than 180 or diastolic more than 120 Past history of congested heart failure or arrhythmia with various severity Sensitivity to the newly-prescribed medications History of severe asthma History of known depression Consuming medications with interactions such as lithium, antiepileptic drugs, chemotherapy Pregnancy Patient unwillingness to enter the study Patients whose prognosis is influenced by another disease

Age
From **18 years** old

Gender
Both

Phase
4

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients consuming renin-angiotensin-aldosterone system inhibitors are recruited in the study using computerized-sequence random codes in 2 groups.

Blinding (investigator's opinion)
Triple blinded

Blinding description

The physicians recruiting patients' data and the statistician are blinded whether the antihypertensive medication will be continued or withheld. A pharmacotherapist will consult with a cardiologist for the patient group whose antihypertensive medication should be changed. At the time of discharge, this medication will be prescribed by the cardiologist who is not blinded and not responsible for data gathering.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice Chancellor in Research Affairs-Tehran University of Medical Sciences

Street address

Sina Hospital, Imam-Khomeini Ave., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1136546911

Approval date

1985-06-17, 1364/03/27

Ethics committee reference number

IR.TUMS.VCR.REC.1399.028

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

corona virus disease 2019

Primary outcomes

1

Description

Death

Timepoint

3 months

Method of measurement

Number of deceased patients

Secondary outcomes

1

Description

ICU admission

Timepoint

6 months

Method of measurement

Number of deceased patients

Intervention groups

1

Description

Intervention group: Discontinuation of agents inhibiting renin-angiotensin-aldosterone system substituting by calcium channel blocker with or without beta-blocker

Category

Treatment - Drugs

2

Description

Control group: Continuation of renin-angiotensin-aldosterone inhibiting agents

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Sina Hospital

Full name of responsible person

Maryam Bahreini

Street address

Sina Hospital, Imam-Khomeini Ave., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1136546911

Phone

+98 21 6312 1413

Email

bahreiniMaryam@gmail.com

Web page address

2

Recruitment center**Name of recruitment center**

Imam-Khomeini hospital

Full name of responsible person

Maryam Bahreini

Street address

Keshavarz blv.

City

Tehran

Province

Tehran

Postal code

1416753955

Phone

+98 21 6690 4848

Email

Imamhospital@tums.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

Street address

Keshavarz Blv., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 6649 2271

Email

ic-research@tums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Maryam Bahreini

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Sina Hospital, Imam-Khomeini Ave., Tehran, Iran

City

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Province

Tehran

Postal code

1136546911

Phone

+98 21 6312 1413

Email

bahreini maryam@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Maryam Bahreini

Position

Associate Professor

Latest degree

Specialist

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not 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

Yes - There is 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

Title and more details about the data/document

Data will be shared if a journal wants to.

When the data will become available and for how long

At the time of publishing the article

To whom data/document is available

Journal editor or reviewers

Under which criteria data/document could be used

In case of a request from journal reviewers or editors

From where data/document is obtainable

They can email me.

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

They can email me.

Comments