Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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-aldestrone system 2) Patients whose medication inhibiting renin-angiotensin-aldestrone 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
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

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
Other areas of specialty/work
Emergency Medicine
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

Person responsible for updating data

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
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

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