Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 2026

Therapeutic Effect of Tenofovir and hydroxychloroquine combination therapy compared to chloroquine alone in patients with COVID-19

Protocol summary

Study aim
evaluating the effectiveness of tenofovir + hydroxychloroquine regiment compared to hydroxychloroquine alone in patients with COVID-19 penumonia

Design
A randomized single-blinded superiority clinical trial with two parallel groups will carry out on 86 patients

Settings and conduct
This study will carry out on patients who were admitted to the acute respiratory disease ward of Ardabil Imam Khomeini hospital which is the referral hospital of the Ardabil province.

Participants/Inclusion and exclusion criteria
A total of 86 patients with COVID-19 induced pneumonia who have been diagnosed according to standard confirmatory tests will be enrolled in this study regarding the aforementioned inclusion and exclusion criteria.

Intervention groups
Patients will randomly allocate into two groups. Individuals in the study group will receive tenofovir + hydroxychloroquine, and patients in the control group will be treated just with hydroxychloroquine.

Main outcome variables
Alleviation of symptoms, recovery, and discharge; Deterioration of symptoms transfer to ICU; Death.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200421047155N1**
Registration date: **2020-04-25, 1399/02/06**
Registration timing: **prospective**

Last update: **2020-04-25, 1399/02/06**
Update count: **0**

Registration date
2020-04-25, 1399/02/06

Registrant information

Name
Sina Parsay

Name of organization / entity

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Iran (Islamic Republic of)

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+98 45 3333 7332

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sinaparsa91@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-29, 1399/02/10

Expected recruitment end date
2020-06-20, 1399/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Therapeutic Effect of Tenofovir and hydroxychloroquine combination therapy compared to chloroquine alone in patients with COVID-19

Public title
Efficacy of tenofovir in covid-19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with COVID-19 pulmonary infection Established diagnosis of COVID-19 with RTPCR Patients older than 18

years

Exclusion criteria:

Reinfection with COVID-19 Pregnancy Patients with immunodeficiency Individuals who are reluctant to participate in study Prior history of allergy to used drugs Documented history of any other medical condition for which the patient require to use a certain medication routinely. Creatinin clearance less than 30 mg/min Oxygen Saturation (SpO2) less than 40% ICU patients

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

Each patient will be randomly allocated into one of the cases or study groups by using the "research randomizer" website facility.

Blinding (investigator's opinion)

Single blinded

Blinding description

All patients will remain unaware of in which group (study or control) they are.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ardabil University of Medical Science

Street address

Department of infectious disease, Imam Khomeini Hospital, Ataii Ave.

City

Ardabil

Province

Ardabil

Postal code

5614693361

Approval date

2020-04-18, 1399/01/30

Ethics committee reference number

IR.AUMS.REC.1399.051

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

vital signs

Timepoint

daily

Method of measurement

direct physical examination

2

Description

body temperature

Timepoint

daily

Method of measurement

thermometer

3

Description

white blood cell count

Timepoint

daily

Method of measurement

blood sample analysis

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: PO Hydroxychloroquine 200 mg and PO tenofovir 300 mg once a day for 7 days

Category

Treatment - Drugs

2

Description

Control group: PO Hydroxychloroquine 200 mg once a day for 7 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital of Ardabil University of Medical Science

Full name of responsible person
Shahram Habibzadeh

Street address
Infectious disease ward, Imam Khomeini Hospital, Ataii Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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http://arums.ac.ir/vcresearch/fa

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Ardabil 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
Ardabil University of Medical Sciences

Full name of responsible person
Shahram Habibzadeh

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Infectious diseases

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Person responsible for updating data

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Researcher

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Medical doctor

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General Practitioner

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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
All of the participants' data reported in the article relative to this trial after deidentification

When the data will become available and for how long
Immediately after publication regarding the publisher's policy

To whom data/document is available
Researchers who provide a methodologically sound proposal.

Under which criteria data/document could be used
Any purpose

From where data/document is obtainable
Shahram Habibzadeh shahramhabibzadeh@gmail.com
Sina Parsay sinaparsa91@gmail.com

What processes are involved for a request to access data/document
Proposals should be directed to one of the above-mentioned email addresses. Requestors also will need to sign a data access agreement.

Comments