Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Safety and Effectiveness of azithromycin in Patients with COVID-19 Referred to zeiaeian Hospital : A clinical trial study

Protocol summary

Study aim
To determine the efficacy and safety of azithromycin in treatment of patients with confirmed covid-19 infection in zeiaeian Hospital, Tehran

Design
Two arm parallel group randomised trial and open lable .

Settings and conduct
The place of work is Ziaian Hospital in Tehran and all eligible patients will be thoroughly informed about the trial and sign an informed consent form; after which they will be randomly put in the two study arms. Patients in each arm of the study will receive a 5-day course of treatment of the mentioned drugs; and the results of their treatments will be compared.

Participants/Inclusion and exclusion criteria
Inclusion criteria:Obtaining informed consent from patient or patient’s legal proxy .over 18 years of age .A documented positive PCR test for SARS-CoV-2 or one of the : Compelling clinical symptoms including: fever, dry cough and dyspnea ,A typically involvement of lungs in HRCT or Spiral CT scanning that attributed to a covid-19 pneumonia . pregnant Patients. a known allergy to chloroquine or hydroxylchloroquinePatients with retinopathy, G6PD deficiency and a prolonged QT interval

Intervention groups
Case group: These patients receive daily azithromycin 500 mg, bi-daily oseltamivir 75, bi-daily lopinavir/ritonavir or in case of adverse gastrointestinal effects daily atazanavir (Kaletra) 400/100 mg and daily 400 mg of hydroxychloroquine; all for 5 days.Control group: These patients receive bi-daily oseltamivir 75, bi-daily lopinavir/ritonavir or atazanavir (Kaletra) 400/100 mg and in case of adverse gasterointestinal effects, daily atazanavir (Kaletra) 400/100 mg and daily 400 mg of hydroxychloroquine; all drugs are administered for five days.

Main outcome variables
fever respiratory rate admission duration need an ICU spo2

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200415047092N1**
Registration date: **2020-04-20, 1399/02/01**
Registration timing: **prospective**

Last update: **2020-04-20, 1399/02/01**
Update count: **0**

Registration date
2020-04-20, 1399/02/01

Registrant information

Name
ehsan sekhavati

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8888 9613

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-24, 1399/02/05

Expected recruitment end date
2020-05-08, 1399/02/19

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Safety and Effectiveness of azithromycin in Patients with COVID-19 Referred to zeiaeian Hospital : A clinical trial study

Public title
The effect of azithromycin in treatment of COVID19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
- Obtaining informed consent from patient or patient's legal proxy for inclusion in this study.- Patients must be over 18 years of age- A documented positive PCR test for SARS-CoV-2 or one of the following criteria:1. Compelling clinical symptoms associated with a covid-19 infection; including: fever, dry cough and dyspnea2. A typically involvement of lungs observed in HRCT or Spiral CT scanning that can be strongly attributed to a covid-19 pneumonia3. Patients that have developed known complications of a covid-19 infection such as acute respiratory distress syndrome (ARDS) or myocarditis.

Exclusion criteria:
pregnancy or nursing Patients whose covid-10 infection has not been proven and have symptoms that can be attributed to either the common cold or influenza and/or have had a positive PCR test for influenza. known allergy to chloroquine or hydroxylchloroquine retinopathy G6PD deficiency prolonged QT interval severe heart failure Pacemaker implantation cardiac arrhythmia

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **110**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients use randomized block-chain, which not only makes Randomization equal in two groups, but also allows patients to be assigned equally to both groups at each stage of the study. These small blocks keep the balance between the two groups and make the number of people in each group similar. In our study, considering that there are two groups, four patients are considered for each block.

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 Tehran University of Medical Sciences

Street address
zeiaeian hospital, abuzar ave.

City
tehran

Province
Tehran

Postal code
1366736511

Approval date
2020-04-08, 1399/01/20

Ethics committee reference number
IR.TUMS.VCR.REC.1399.165

Health conditions studied

1

Description of health condition studied
SARS-COV2 ASSOCIATED INFECTION

ICD-10 code
U07.1

ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
peripheral capillary oxygen saturation

Timepoint
At the beginning of the visit and daily during admission

Method of measurement
pulse oximeter

2

Description
Admission duration

Timepoint
From the beginning of the hospital visit to the discharge

Method of measurement
Questionnaire

3

Description
Fever

Timepoint
At the beginning of the visit and daily during admission

Method of measurement
Mercury thermometer

4

Description
Need to ICU admission
Timepoint
During admission
Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: These patients receive daily azithromycin 500 mg, bi-daily oseltamivir 75, bi-daily lopinavir/ritonavir or in case of adverse gastrointestinal effects daily atazanavir (Kaletra) 400/100 mg and daily 400 mg of hydroxychloroquine; all for 5 days.
Category
Treatment - Drugs

2

Description
Control group: These patients receive bi-daily oseltamivir 75, bi-daily lopinavir/ritonavir or atazanavir (Kaletra) 400/100 mg and in case of adverse gasterointestinal effects, daily atazanavir (Kaletra) 400/100 mg and daily 400 mg of hydroxychloroquine; all drugs are administered for five days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Zeiaeian hospital
Full name of responsible person
Ehsan Sekhavati Moghadam
Street address
Zeiaeian hospital ,Abuzar Ave,Tehran
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Dr.esekhavati@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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Research Departmet of Tehran University Medical Science ,Keshavarz Blvd
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Vcr@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
Ehsan Sekhavati Moghadam
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Email
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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
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
Yes - There is a plan to make this available
Title and more details about the data/document
A part of the data, such as information about the main consequence or similar, can be shared.
When the data will become available and for how long
Start of access from 1399
To whom data/document is available
Researchers working in academic and scientific institutions, people who are also engaged in industry
Under which criteria data/document could be used
Mentioning the source and Permission and consultation with the responsible author are mandatory
From where data/document is obtainable
EMAIL DR.FERESHTEGHIASVAND
What processes are involved for a request to access data/document
Send emails and mention the required files and the reason for the request and description of using the data
Comments