# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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**
dr.esekhavati@gmail.com

**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
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Zeiaeian hospital ,Abuzar Ave,Tehran
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Tehran University of Medical Sciences
**Full name of responsible person**
Mohammad Ali Sahraian
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Research Departmet of Tehran University Medical Science ,Keshavarz Blvd
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+98 21 8163 3698
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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 scientific inquiries

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## Person responsible for updating data

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**Province**
Tehran
**Postal code**
1419733141
**Phone**
02161190
**Email**
Ghiasvand_62@yahoo.com

## 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**