

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Dec 2021

Evaluation and comparison of the effectiveness of Hydroxychloroquin versus Clarithromycin in recovery of dyspnea and Caught at the end of the acute phase of COVID-19 treatment

Protocol summary

Study aim

Comparison of the effectiveness of Hydroxychloroquine versus Clarithromycin in Patients with Persistent dyspnea and cough at the end of acute phase COVID-19

Design

The study is a clinical trial that is performed with a Parallel design as a pilot in three groups and each group contains 15 patients. Classification of patients into three groups is done via a simple random method by selecting sealed envelopes containing A, B, C cards. This study is done without blinding.

Settings and conduct

Patients with inclusion criteria, are randomly placed in three groups. In the initial visit of patients, a detailed history of demographic characteristics and the disease in the acute phase will be obtained. Laboratory tests beside baseline CT-SCAN are requested and patients' dyspnea and pulmonary function will be measured. We give hydroxychloroquine, clarithromycin in two interventional groups and we give nothing in control group. The assessment is performed without blinding. At the end of 4 weeks, reassessment of dyspnea and cough - laboratory findings - and lung function are performed separately in each group and compared with each other.

Participants/Inclusion and exclusion criteria

The main inclusion criteria is all patients aged between 20 - 50 years with a history of coronavirus who have dyspnea and cough beside evidence of involvement in chest CT despite after two weeks of recovery. The most important exclusion criteria is patients having underlying cardiopulmonary diseases or they are taking medications which interact with drugs that have been selected in this study.

Intervention groups

Intervention group 1: Tablet Hydroxychloroquine 200 mg every 12 hours for one month from Roozdaroo company
Intervention group 2: Capsule Clarithromycin 500 mg

every 12 hours for one month from Tehran Shimi company Control Group without Medication

Main outcome variables

Dyspnea, cough

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200718048129N1**

Registration date: **2020-08-11, 1399/05/21**

Registration timing: **prospective**

Last update: **2020-08-11, 1399/05/21**

Update count: **0**

Registration date

2020-08-11, 1399/05/21

Registrant information

Name

sima bahrami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2267 8057

Email address

bahrami.s@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation and comparison of the effectiveness of Hydroxychloroquin versus Clarithromycin in recovery of dyspnea and Caught at the end of the acute phase of COVID-19 treatment

Public title
Evaluation of the effectiveness of Hydroxychloroquine and Clarithromycin in dyspnea and caught caused by COVID-19 in recovery phase

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with definitive diagnosis of COVID19 were hospitalized and treated Patients with COVID19 who still have dyspnea and cough two weeks after discharge from the hospital Patients with COVID19 who continue to have lung involvement on CT SCAN two weeks after discharge

Exclusion criteria:
Patients with comorbidities such as chronic heart or lung disease before COVID19 The need for long-term use of drugs that have an irreversible interaction with the drugs used in the plan.

Age
From **20 years** old to **50 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
In our study, the simple randomization method is used as follows. A number of sealed envelopes in which study groups with letters A, intervention group with hydroxychloroquine, group B, intervention with clarithromycin and group C, including the control group, have been identified. The number of envelopes in each group is equal in number. The cards are merged and a card is randomly selected for each referring patient, thus assigning the patient to one of the groups. The removed card is then returned to the other cards. This process continues until a random sequence is reached according to the sample size in each group.

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 Iran university of Medical Sciences

Street address

Floor5,Headquarters,Iran university of Medical science,between Chamran and sheikh Fazlollah,Hemmat Highway,Tehran

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2020-07-04, 1399/04/14

Ethics committee reference number

IR.IUMS.FMD.REC.1399.244

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID19 ,virus identified

Primary outcomes

1

Description

Dyspnea

Timepoint

Beginning of the study (before the intervention), 14, 30 days after the start of the study

Method of measurement

Medical Research Council(MRC)

2

Description

cough

Timepoint

Beginning of the study (before the intervention), 14, 30 days after the start of the study

Method of measurement

visual analogue scale(vas)

Secondary outcomes

1

Description

lung function.

Timepoint

At the beginning of the study (before the intervention) and 30 days later at the end of the study

Method of measurement

six minute walk test(6MW)

Intervention groups

1

Description

Intervention group 1: Hydroxychloroquine tablets 200 mg every 12 hours for one month from Rooz daroo company

Category

Treatment - Other

2

Description

Intervention group 2: Clarithromycin 500 mg capsules every 12 hours for one month from Tehran shimi company

Category

Treatment - Other

3

Description

Control group: without receiving medication during a one-month follow-up

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasool Hospital

Full name of responsible person

Dr Sima Bahrami

Street address

Hazrat Rasool Hospital, Niayesh St, Satarkhan St, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Seyed Abbas Motavlian

Street address

The headquarters, 5 floor, Iran university of medical sciences, next to Milad Tower, Hemmat highway, Tehran

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Sima Bahrami

Position

Subspecialized assistant

Latest degree

Specialist

Other areas of specialty/work

Immunology

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Person responsible for scientific inquiries

Contact

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Specialist
Other areas of specialty/work
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Person responsible for updating data

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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 provided data after unidentifying the subjects, include demographic information and characteristics of their disease in the acute phase, along with a description of the first visit and tests taken from patients at that time. The type of performed intervention for each patient and patients' clinical condition change after Intervention practices and finally the method of data analysis are the other documents which can be provided.

When the data will become available and for how long

Access started 6 months after the results were published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

In order to conduct further research, any analysis other than those used in this study is acceptable with the permission of the research agent.

From where data/document is obtainable

Dr. Sima Bahrami Address: Allergy and Immunology Clinic, Hazrat Rasoul Hospital, Niayesh St - Sattarkhan Av. Tehran Phone: 09127305773 Email: bahrami.s@iums.ac.ir

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

The applicant can introduce himself / herself by e-mail and provide sufficient and documented reasons for receiving the study information. The research agent can check this information in a period of two weeks and if he is sure that the request is correct, he will send the requested items to the applicant

Comments