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 Caugh 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 interventionals 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 Caugh at the end of the acute phase of COVID-19 treatment

Public title

Evaluation of the effectiveness of Hydroxychloroquine and Clarithromycin in dyspnea and caugh 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 dyspena 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 fram 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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bahrami.s@iums.ac.ir

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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research-m@iums.ac.ir
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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Hazrate Rasoole Akram hospital,Niayesh St,Satarkhan Av,Tehran
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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