Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Dec 2021

Clinical Trial on Diphenhydramine Compound in Covid-19 Treatment

Protocol summary

Study aim
Clinical Trial on Diphenhydramine Compound in Covid-19 Treatment

Design
This clinical trial is a double-blinded case-control randomized study on 120 patients. Permuted block randomization technique was used for patients randomization.

Settings and conduct
This study will be performed in Imam Ali hospital at the first 6 months of the year. Statistical analyses will be accomplished using STATA software. This study is designed double-blinded (patients and physicians). Patients of each group (case or control) will be hospitalized in a specific place and do not have any contact with patients of the opposite group.

Participants/Inclusion and exclusion criteria
Patients between 18-70 years admmited to the hospital whose diseases were confirmed by CT, RT-PCR.

Intervention groups
Diphenhydramine Compound treatment group receives standard treatment and Dighenhydramin treatment group receives standard treatment. adverse effects and desired effects will be assessed.

Main outcome variables
Clinic and Para clinic (chest ct scan and PCR)findings in COViD-19 patients. Mortality and morbidity rate in COViD-19 patinets. Duration of hospitalization.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200504047298N3**
Registration date: **2020-09-09, 1399/06/19**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-09, 1399/06/19**
Update count: **0**

Registration date
2020-09-09, 1399/06/19

Registrant information
Name
Zeinab Siami
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 4602 2136
Email address
z.siami@abzums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-08-22, 1399/06/01
Expected recruitment end date
2020-10-22, 1399/08/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Clinical Trial on Diphenhydramine Compound in Covid-19 Treatment

Public title
Effect of Diphenhydramine Compound in Covid-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Confirmed Covid-19 Infection Age between 18_70 years old
Exclusion criteria:
Cardiovascular disease non confirmed patients Addicted

patient

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients randomized classification into standard treatment group and case group was performed using permuted block randomization. in this study, four-unit blocks were used. Using R software, a chain of randomized numbers comprising one to six are created to reach the desired sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients, researchers, and health workers were blind. This study is designed double-blinded. Patients of each group (case or control) will be hospitalized in a specific place and do not have any contact with patients of the opposite group. Besides, a member of the research team and a doctor of infectious diseases will prescribe according to assigned treatment codes.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Alborz University of Medical Sciences

Street address

Taleghani Boulevard,Taleghani square ,Karaj,Iran

City

Karaj

Province

Alborz

Postal code

3149779453

Approval date

2020-04-21, 1399/02/02

Ethics committee reference number

IR.ABZUMS.REC.1399.079

Health conditions studied

1

Description of health condition studied

Covid-19

ICD-10 code

U07.1

ICD-10 code description

virus identified’ is assigned to a disease diagnosis of COVID-19 confirmed by laboratory testing.

Primary outcomes

1

Description

Change of involment of lung in HRCT(High-resolution computed tomography)

Timepoint

Day 0 and 7 Days later

Method of measurement

HRCT(High-resolution computed tomography)

2

Description

Change of viral load in Real Time PCR

Timepoint

Day 0 and 7 days later

Method of measurement

Real Time PCR nasopharengeal soap

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:According to the inclusion criteria and in addition to the treatments recommended in the national guideline, all patients with Quid-19, who were divided into three groups based on clinical symptoms, mild, moderate and severe, Diphenhydramine Compound syrup is prescribed in a dose of 10 cc. It lasts every 8 hours for 7 days. Then the patient's clinical symptoms and load of PCR test and lung CT scan of the patient are evaluated at 7-day intervals

Category

Treatment - Drugs

2

Description

Control group: According to the inclusion criteria and in addition to the treatments recommended in the national guideline, all patients with Quid-19, who were divided into three groups based on clinical symptoms, mild, moderate and severe, Diphenhydramine syrup is

prescribed in a dose of 10 cc. It lasts every 8 hours for 7 days. Then the patient's clinical symptoms and load of PCR test andlung CT scan of the patient are evaluated at 7-day intervals.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Ali hospital

Full name of responsible person
Zeinab Siami

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Taleghani Boulevard,Taleghani square ,Karaj,Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Karaj University of Medical Sciences

Full name of responsible person
Mohammad Noorisepehr

Street address
Research center.Safarian Alley,Golshahr Avenue ,Karaj,Iran

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3198764653

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Research@abzums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Karaj 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
Karaj University of Medical Sciences

Full name of responsible person
Zeinab Siami

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Infectious diseases

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Person responsible for scientific inquiries

Contact

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Position
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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
Not applicable

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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
In internet for general population because of importance of covid_19

When the data will become available and for how long
5 years

To whom data/document is available
General population

Under which criteria data/document could be used
General

From where data/document is obtainable
Internet

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

Comments