

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

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 admitted to the hospital whose diseases were confirmed by CT, RT-PCR.

Intervention groups

Diphenhydramine Compound treatment group receives standard treatment and Diphenhydramine 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 patients. 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 involvement 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 nasopharyngeal 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 and lung 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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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****Name of organization / entity**

Karaj University of Medical Sciences

Full name of responsible person

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Position

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Person responsible for updating data**Contact****Name of organization / entity**

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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