

# 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 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

**Street address**

Taleghani Boulevard,Taleghani square ,Karaj,Iran

**City**

Karaj

**Province**

Alborz

**Postal code**

3149779453

**Phone**

+98 26 3271 7149

**Email**

z.siami@abzums.ac.ir

**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

**City**

Karaj

**Province**

Alborz

**Postal code**

3198764653

**Phone**

+98 26 3271 7149

**Email**

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

**Street address**

Karaj.azimieh.emam ali hospital.infection disease department

**City**

Karaj

**Province**

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**Postal code**

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Karaj University of Medical Sciences

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**Fax****Email**

z.siami@abzums.ac.ir

**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**