

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Oct 2020

Effect of plasma of patients recovered from covid-19 versus control group on treatment of covid-19: a randomized clinical trial

Protocol summary

Registration timing: **prospective**

Study aim

To assess the effect of plasma of patients recovered from covid-19 versus control group on treatment of covid-19

Last update: **2020-04-27, 1399/02/08**

Update count: **0**

Design

This is a randomized clinical trial, phase II, in which 100 eligible patients will be randomly assigned to the intervention and control groups

Registration date

2020-04-27, 1399/02/08

Settings and conduct

The eligible patients with covid-19 referring to the Sina Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization.

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 65 years, Moderate to severe covid-19 disease, Exclusion criteria: Pregnancy, IGA deficiency

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-14, 1399/02/25

Expected recruitment end date

2020-06-20, 1399/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Intervention groups

Intervention group: Routine care (For outpatients: 250 mg chloroquine tablets every 12 hours for the first day and then every day for up to 6 days; for inpatients: tablet Lupinavir 200 mg and tablet Ritonavir 50 mg every 12 hours for 14 days) plus plasma of patients recovered from covid-19 500 U every week for at least 3 weeks
Control group: Just routine care (For outpatients: 250 mg chloroquine tablets every 12 hours for the first day and then every day for up to 6 days; for inpatients: tablet Lupinavir 200 mg and tablet Ritonavir 50 mg every 12 hours for 14 days)

Main outcome variables

Primary outcome: Dyspnea, fever, cough with

Scientific title

Effect of plasma of patients recovered from covid-19 versus control group on treatment of covid-19: a randomized clinical trial

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N353**

Registration date: **2020-04-27, 1399/02/08**

Public title

Effect of plasma of patients recovered from covid-19 versus control group on treatment of covid-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 65 years, Moderate to severe covid-19 disease,

Exclusion criteria:

Pregnancy, IGA deficiency

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

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 Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2020-04-11, 1399/01/23

Ethics committee reference number

IR.UMSHA.REC.1399.037

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

Dyspnea

Timepoint

Every day for 3 weeks

Method of measurement

With taking history and physical examination

2

Description

Fever

Timepoint

Every day for 3 weeks

Method of measurement

With physical examination

3

Description

Cough

Timepoint

Every day for 3 weeks

Method of measurement

With taking history

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine care (For outpatients: 250 mg chloroquine tablets every 12 hours for the first day and then every day for up to 6 days; for inpatients: tablet Lupinavir 200 mg and tablet Ritonavir 50 mg every 12 hours for 14 days) plus plasma of patients recovered from covid-19 500 U every week for at least 3 weeks

Category

Treatment - Drugs

2**Description**

Control group: Just routine care (For outpatients: 250 mg chloroquine tablets every 12 hours for the first day and then every day for up to 6 days; for inpatients: tablet Lupinavir 200 mg and tablet Ritonavir 50 mg every 12 hours for 14 days)

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Sina Hospital in Hamadan city

Full name of responsible person

Samereh Ghelichkhani

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Sina Hospital, Mirzadeh Eshghi Ave.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

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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

Hamedan 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**

Hamedan University of Medical Sciences

Full name of responsible person

Samereh Ghelichkhani

Position

MSc in Nursery

Latest degree

Master

Other areas of specialty/work

Nursery

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School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Ebrahim Jalili

Position

Emergency Medicine Specialist

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

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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)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available