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

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

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

Settings and conduct
The eligible patients with covid-19referring 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.

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

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

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N353**
Registration date: **2020-04-27, 1399/02/08**
Registration timing: **prospective**

Last update: **2020-04-27, 1399/02/08**
Update count: **0**

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

Registrant information

Name
Jalal Poorolajal

Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 81 1838 0090

Email address
poorolajal@umsha.ac.ir

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

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

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
Street address
Sina Hospital, Mirzadeh Eshghi Ave.
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3827 4184
Email
sa.ghelichkhani@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Saeid Bashirian
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0717
Email
info.research@umsha.ac.ir
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
Street address
School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0572
Email
sa.ghelichkhani@gmail.com

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
Street address
School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.
City
Hamadan
Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

jalili.dr@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

Street address

School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0090

Email

poorolajal@umsha.ac.ir

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