

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Oct 2020

Evaluating the effect of intravenous hydrocortisone, methylprednisolone, and dexamethasone in treatment of patients with moderate to severe acute respiratory distress syndrome caused by COVID-19: A double blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of intravenous hydrocortisone, methylprednisolone, and dexamethasone in the treatment of patients with moderate to severe acute respiratory distress syndrome caused by COVID-19

Design

This is a double-blind randomized clinical trial, phase II, in which 81 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients with moderate to severe acute respiratory distress syndrome caused by 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. This trial will be double-blinded so that neither patients nor the physician examining the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 70 years, Hospitalized in the intensive care unit in less than past 48 hours, Mild to moderate acute respiratory distress syndrome due to COVID-19, Bilateral pulmonary infiltration in chest X-ray or CT-scan, Respiratory distress with more than 24 breathe per minute Exclusion criteria: Pregnancy or breastfeeding, Cardiopulmonary edema, Severe acute respiratory distress syndrome, Using antioxidant drugs, Chronic liver or renal disease, Contraindication of N-acetyl cysteine

Intervention groups

Intervention group 1: Routine care plus intravenous hydrocortisone 50 mg every 6 hours for 5 days
Intervention group 2: Routine care plus intravenous methylprednisolone 40 mg every 12 hours for 5 days
Intervention group 3: Routine care plus intravenous dexamethasone 20 mg daily for 5 days

Main outcome variables

Primary outcome: Need to mechanical ventilation, the patient's clinical status, the mortality rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N354**

Registration date: **2020-05-12, 1399/02/23**

Registration timing: **prospective**

Last update: **2020-05-12, 1399/02/23**

Update count: **0**

Registration date

2020-05-12, 1399/02/23

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

2020-06-04, 1399/03/15

Expected recruitment end date

2020-08-05, 1399/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of intravenous hydrocortisone, methylprednisolone, and dexamethasone in treatment of patients with moderate to severe acute respiratory distress syndrome caused by COVID-19: A double blind randomized clinical trial

Public title

Evaluating the effect of intravenous hydrocortisone, methylprednisolone, and dexamethasone in treatment of patients with moderate to severe acute respiratory distress syndrome caused by COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of 18 to 70 years, Hospitalized in intensive care unit in less than past 48 hours, Mild to moderate acute respiratory distress syndrome due to COVID-19, Bilateral pulmonary infiltration in chest X-ray or CT-scan, Respiratory distress with more than 24 breathe per minute

Exclusion criteria:

Pregnancy or breastfeeding, Cardiopulmonary edema, Severe acute respiratory distress syndrome, Using antioxidant drugs, Chronic liver or renal disease, Contraindication of N-acetyl cysteine

Age

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

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **81**

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 six sheets of paper, writing on two sheets the name of the intervention 1 and on two other sheets the name of the intervention 2 and on the third two sheets the name of intervention 3. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all six sheets are drawn. The six paper

sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)

Double blinded

Blinding description

The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as double-blind

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

2020-05-09, 1399/02/20

Ethics committee reference number

IR.UMSHA.REC.1399.152

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**

Need to mechanical ventilation

Timepoint

Within 28 days after the intervention

Method of measurement

By physical examination

2

Description

The patient's clinical status

Timepoint

Within 28 days after the intervention

Method of measurement

Based on the World Health Organization's 7-score system

3

Description

Mortality rate

Timepoint

Within 28 days after the intervention

Method of measurement

Based on medical document

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Routine care plus intravenous hydrocortisone 50 mg every 6 hours for 5 days

Category

Treatment - Drugs

2

Description

Intervention group 2: Routine care plus intravenous methylprednisolone 40 mg every 12 hours for 5 days

Category

Treatment - Drugs

3

Description

Intervention group 3: Routine care plus intravenous dexamethasone 20 mg daily for 5 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital in Hamadan city

Full name of responsible person

Dr Abbas Taher

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

t_anesthesia@yahoo.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

Dr Abbas Taher

Position

Anesthesiologist

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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

t_anesthesia@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Fariba Keramat

Position

Infectious Diseases Specialist

Latest degree

Medical doctor

Other areas of specialty/work

Infectious diseases

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

faribakeramat@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