Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 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)

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+98 81 1838 0090

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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
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6517838695
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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
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave
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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
Dr Abbas Taher
Position
Anesthesiologist
Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

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Dr. Fariba Keramat

Position

Infectious Diseases Specialist

Latest degree

Medical doctor

Other areas of specialty/work

Infectious diseases

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Person responsible for updating data

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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

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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