Vitamin C Infusion for the Treatment of Severe 2019-nCoV Infected Pneumonia

ClinicalTrials.gov Identifier: NCT04264533

Recruitment Status : Recruiting
First Posted : February 11, 2020
Last Update Posted : March 10, 2020

See **Contacts and Locations**

Sponsor:
ZhiYong Peng

Information provided by (Responsible Party):
ZhiYong Peng, Zhongnan Hospital

Study Details | Tabular View | No Results Posted | Disclaimer | How to Read a Study Record

Study Description

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Brief Summary:

2019 new coronavirus (2019-nCoV) infected pneumonia, namely severe acute respiratory infection (SARI) has caused global concern and emergency. There is a lack of effective targeted antiviral drugs, and symptomatic supportive treatment is still the current main treatment for SARI.

Vitamin C is significant to human body and plays a role in reducing inflammatory response and preventing common cold. In addtion, a few studies have shown that vitamin C deficiency is related to the increased risk and severity of influenza infections.

We hypothize that Vitamin C infusion can help improve the prognosis of patients with SARI. Therefore, it is necessary to study the clinical efficacy and safety of vitamin C for the clinical management of SARI through randomized controlled trials during the current epidemic of SARI.

Condition or disease	Intervention/treatment	Phase
Vitamin C Pneumonia, Viral Pneumonia, Ventilator-Associated	Drug: VC Drug: Sterile Water for Injection	Phase 2

Detailed Description:

At the end of 2019, patients with unexplained pneumonia appeared in Wuhan, China. At 21:00 on January 7, 2020, a new coronavirus was detected in the laboratory, and the detection of pathogenic nucleic acids was completed at 20:00 on January 10. Subsequently, the World Health Organization officially named the new coronavirus that caused the pneumonia epidemic in Wuhan as 2019 new coronavirus (2019-nCoV), and the pneumonia was named severe acute respiratory infection (SARI). Up to February 4, 2020, over 20000 cases have been diagnosed in China, 406 of which have died, and 154 cases have been discovered in other countries around the world. Most of the deaths were elderly patients or patients with severe underlying diseases. SARI has caused global concern and emergency.

Statistics of the 41 patients with SARI published in JAMA initially showed that 13 patients were transferred into the ICU, of which 11 (85%) had ARDS and 3 (23%) had shock. Of these, 10 (77%) required mechanical ventilation support, and 2 (15%) required ECMO support. Of the above 13 patients, 5 (38%) eventually died and 7 (38%) were transferred out of the ICU. Viral pneumonia is a dangerous condition with a poor clinical prognosis. For most viral infections, there is a lack of effective targeted antiviral drugs, and symptomatic supportive treatment is still the current main treatment.

Vitamin C, also known as ascorbic acid, has antioxidant properties. When sepsis happens, the cytokine surge caused by sepsis is activated, and neutrophils in the lungs accumulate in the lungs, destroying alveolar capillaries. Early clinical studies have shown that vitamin C can effectively prevent this process. In addition, vitamin C can help to eliminate alveolar fluid by preventing the activation and accumulation of neutrophils, and reducing alveolar epithelial water channel damage. At the same time, vitamin C can prevent the formation of neutrophil extracellular traps, which is a biological event of vascular injury caused by neutrophil activation. Vitamins can effectively shorten the duration of the common cold. In extreme conditions (athletes, skiers, art workers, military exercises), it can effectively prevent the common cold. And whether vitamin C also has a certain protective effect on influenza patients, only few studies have shown that vitamin C deficiency is related to the increased risk and severity of influenza infections. In a controlled but non-randomized trial, 85% of the

252 students treated experienced a reduction in symptoms in the high-dose vitamin C group (1g / h at the beginning of symptoms for 6h, followed by 3 * 1g / day). Among patients with sepsis and ARDS, patients in the high-dose vitamin group did not show a better prognosis and other clinical outcomes. There are still some confounding factors in the existing research, and the conclusions are different.

Therefore, during the current epidemic of SARI, it is necessary to study the clinical efficacy and safety of vitamin C for viral pneumonia through randomized controlled trials.

Study Design

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Study Type :

Interventional (Clinical Trial)

Estimated Enrollment :

140 participants

Allocation:

Randomized

Intervention Model:

Parallel Assignment

Masking:

Triple (Participant, Care Provider, Outcomes Assessor)

Primary Purpose:

Treatment

Official Title:

Vitamin C Infusion for the Treatment of Severe 2019-nCoV Infected Pneumonia: a Prospective Randomized Clinical Trial

Actual Study Start Date :

February 14, 2020

Estimated Primary Completion Date :

September 30, 2020

Estimated Study Completion Date :

September 30, 2020

Resource links provided by the National Library of Medicine

MedlinePlus related topics: Pneumonia Vitamin C

Drug Information available for: Ascorbic acid Sodium ascorbate Magnesium ascorbate

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Experimental: VC 12g Vitamin C+sterile water for injection; total volume: 50ml. 12ml/h; infusion pump； q12h.	Drug: VC 12g Vitamin C will be infused in the experimental group twice a day for 7 days by the infusion pump with a speed of 12ml/h. Other Name: Vitamin C
Placebo Comparator: Sterile water for injection 50ml water for injection. 12ml/h; infusion pump; q12h.	Drug: Sterile Water for Injection 50ml sterile water for injection will be infused in the placebo comparator group twice a day for 7 days by the infusion pump with a speed of 12ml/h.

Outcome Measures

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Primary Outcome Measures :

1. Ventilation-free days [Time Frame: on the day 28 after enrollment]

   days without ventilation support during 28 days after patients' enrollment

Secondary Outcome Measures :

1. 28-days mortality [Time Frame: on the day 28 after enrollment]

   wether the patient survives

2. ICU length of stay [Time Frame: on the day 28 after enrollment]

   days of the patients staying in the ICU

3. Demand for first aid measuments [Time Frame: on the day 28 after enrollment]

   the rate of CPR

4. Vasopressor days [Time Frame: on the day 28 after enrollment]

days of using vasopressors

5. Respiratory indexes [Time Frame: on the day 10 and 28 after enrollment]

   P O2/Fi O2 which reflects patients' respiratory function

6. Ventilator parameters [Time Frame: on the day 10 and 28 after enrollment]

   Ecmo or ventilator

7. APACHE II scores [Time Frame: on the day 10 after enrollment]

   Acute Physiology and Chronic Health Evaluation

8. SOFA scores [Time Frame: on the day 10 after enrollment]

   Sepsis-related Organ Failure Assessment

Eligibility Criteria

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Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study:

All

Accepts Healthy Volunteers:

No

Criteria

Inclusion Criteria:

1. ≥ 18 years old;
2. Diagnosed as serious or critical SARI (according to the 4th version of Diagnosis and Clinical management of 2019-nCoV infected pneumonia);
3. Being treated in the ICU.

Exclusion Criteria:

1. Allergic to vitamin C;
2. Dyspnea due to cardiogenic pulmonary edema;
3. Pregnant or breastfeeding;
4. Expected life is less than 24 hours;
5. There is a state of tracheotomy or home oxygen therapy in the past;
6. Previously complicated with end-stage lung disease, end-stage malignancy, glucose-6-phosphate dehydrogenase deficiency, diabetic ketoacidosis, and active kidney stone disease;
7. The patient participates in another clinical trial at the same time.

Contacts and Locations

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To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04264533***

Contacts

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Locations

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Recruiting

Sponsors and Collaborators

ZhiYong Peng

Investigators

Principal Investigator: Zhiyong Peng, professor Wuhan University

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Responsible Party:

ZhiYong Peng, Professor; Chief physician, Zhongnan Hospital

ClinicalTrials.gov Identifier:

NCT04264533 History of Changes

Other Study ID Numbers:

2020001

First Posted:

February 11, 2020 Key Record Dates

Last Update Posted:

March 10, 2020

Last Verified:

February 2020

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:

No

Studies a U.S. FDA-regulated Drug Product:

No

Studies a U.S. FDA-regulated Device Product:

No

Keywords provided by ZhiYong Peng, Zhongnan Hospital:

Vitamin C

2019-novel coronavirus pneumonia

Severe acute respiratory infection

Additional relevant MeSH terms:

Pneumonia, Ventilator-Associated
Pneumonia, Viral
Pneumonia
Lung Diseases
Respiratory Tract Diseases
Respiratory Tract Infections
Cross Infection
Infection
Virus Diseases
Vitamins
Ascorbic Acid
Micronutrients
Nutrients
Growth Substances
Physiological Effects of Drugs
Antioxidants
Molecular Mechanisms of Pharmacological Action
Protective Agents