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

Tracking Information

First Submitted Date ICMJE
February 4, 2020
First Posted Date ICMJE

February 11, 2020

Last Update Posted Date

March 10, 2020

Actual Study Start Date ICMJE

February 14, 2020

Estimated Primary Completion Date

September 30, 2020 (Final data collection date for primary outcome measure)

Current Primary Outcome Measures ICMJE
(submitted: February 8, 2020)

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

days without ventilation support during 28 days after patients' enrollment

Original Primary Outcome Measures ICMJE

Same as current

Change History

Complete list of historical versions of study NCT04264533 on ClinicalTrials.gov Archive Site

Current Secondary Outcome Measures ICMJE
(submitted: March 6, 2020)

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

  wether the patient survives
- ICU length of stay [Time Frame: on the day 28 after enrollment]

  days of the patients staying in the ICU
- Demand for first aid measuments [Time Frame: on the day 28 after enrollment]

  the rate of CPR
- Vasopressor days [Time Frame: on the day 28 after enrollment]

  days of using vasopressors
- Respiratory indexes [Time Frame: on the day 10 and 28 after enrollment]

  P O2/Fi O2 which reflects patients' respiratory function
- Ventilator parameters [Time Frame: on the day 10 and 28 after enrollment]

  Ecmo or ventilator

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

  Acute Physiology and Chronic Health Evaluation
- SOFA scores [Time Frame: on the day 10 after enrollment]

  Sepsis-related Organ Failure Assessment

Original Secondary Outcome Measures ICMJE
(submitted: February 8, 2020)

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

  wether the patient survives
- ICU length of stay [Time Frame: on the day 28 after enrollment]

  days of the patients staying in the ICU
- Demand for first aid measuments [Time Frame: on the day 28 after enrollment]

  t t the rate of CPR
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  days of using vasopressors
- Respiratory indexes [Time Frame: on the day 10 and 28 after enrollment]

  P O2/Fi O2 which reflects patients' respiratory function
- Ventilator parameters [Time Frame: on the day 10 and 28 after enrollment]

  Ecmo or ventilator
- APACHE II scores [Time Frame: on the day 10 after enrollment]

  Acute Physiology and Chronic Health Evaluation
- SOFA scores [Time Frame: on the day 10 after enrollment]

  Sepsis-related Organ Failure Assessment

Current Other Pre-specified Outcome Measures

Not Provided

Original Other Pre-specified Outcome Measures

Not Provided

Descriptive Information

Brief Title ICMJE

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

Official Title ICMJE

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

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.

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 Type ICMJE

Interventional

Study Phase ICMJE

Phase 2

Study Design ICMJE

Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: Triple (Participant, Care Provider, Outcomes Assessor)
Primary Purpose: Treatment

Condition ICMJE

- Vitamin C
- Pneumonia, Viral
- Pneumonia, Ventilator-Associated

Intervention ICMJE

- 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

- 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.

Study Arms ICMJE

- Experimental: VC

  12g Vitamin C+sterile water for injection; total volume: 50ml. 12ml/h; infusion pump；q12h.

  Intervention: Drug: VC

- Placebo Comparator: Sterile water for injection

  50ml water for injection. 12ml/h; infusion pump; q12h.

  Intervention: Drug: Sterile Water for Injection

Publications *

Not Provided

*** Includes publications given by the data provider as well as publications identified by ClinicalTrials.gov Identifier (NCT Number) in Medline.**

Recruitment Information

Recruitment Status ICMJE

Recruiting

Estimated Enrollment ICMJE
(submitted: February 8, 2020)

140

Original Estimated Enrollment ICMJE

Same as current

Estimated Study Completion Date ICMJE

September 30, 2020

Estimated Primary Completion Date

September 30, 2020 (Final data collection date for primary outcome measure)

Eligibility Criteria ICMJE

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.

Sex/Gender ICMJE

Sexes Eligible for Study:
All

Ages ICMJE

18 Years and older (Adult, Older Adult)

Accepts Healthy Volunteers ICMJE

No

Contacts ICMJE

Contact: Zhiyong Peng, professor
+8618672396028
pengzy5@hotmail.com

Listed Location Countries ICMJE

China

Removed Location Countries

Administrative Information

NCT Number ICMJE

NCT04264533

Other Study ID Numbers ICMJE

2020001

Has Data Monitoring Committee

Not Provided

U.S. FDA-regulated Product

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

No

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

No

IPD Sharing Statement ICMJE

Plan to Share IPD:

No

Responsible Party

ZhiYong Peng, Zhongnan Hospital

Study Sponsor ICMJE

ZhiYong Peng

Collaborators ICMJE

Not Provided

Investigators ICMJE

Principal Investigator:

Zhiyong Peng, professor

Wuhan University

PRS Account

Zhongnan Hospital

Verification Date

February 2020

ICMJE **Data element required by the International Committee of Medical Journal Editors and the World Health Organization ICTRP**