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

ClinicalTrials.gov Identifier: NCT04264533

Recruitment Status : Not yet recruiting
First Posted : February 11, 2020
Last Update Posted : February 11, 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	February 11, 2020
Estimated Study Start Date ICMJE	February 10, 2020
Estimated Primary Completion Date	September 30, 2020 (Final data collection date for primary outcome m
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' e
Original Primary Outcome Measures ICMJE	*Same as current*
Change History	No Changes Posted
Current 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 a enrollment] t t 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 e P O2/Fi O2 which reflects patients' respiratory function • Ventilator parameters [Time Frame: on the day 10 and 28 after 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	*Same as current*
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 Pne
Official Title ICMJE	Vitamin C Infusion for the Treatment of Severe 2019-nCoV Infected Pne Prospective Randomized Clinical Trial
Brief Summary	2019 new coronavirus (2019-nCoV) infected pneumonia, namely s respiratory infection (SARI) has caused global concern and emerge lack of effective targeted antiviral drugs, and symptomatic support still the current main treatment for SARI. Vitamin C is significant to human body and plays a role in reducing response and preventing common cold. In addtion, a few studies h vitamin C deficiency is related to the increased risk and severity of infections. We hypothize that Vitamin C infusion can help improve the progno with SARI. Therefore, it is necessary to study the clinical efficacy a vitamin C for the clinical management of SARI through randomized trials during the current epidemic of SARI.
Detailed Description	At the end of 2019, patients with unexplained pneumonia appeare China. At 21:00 on January 7, 2020, a new coronavirus was detect laboratory, and the detection of pathogenic nucleic acids was com on January 10. Subsequently, the World Health Organization officia

new coronavirus that caused the pneumonia epidemic in Wuhan a coronavirus (2019-nCoV), and the pneumonia was named severe a infection (SARI). Up to February 4, 2020, over 20000 cases have b in China, 406 of which have died, and 154 cases have been disco countries around the world. Most of the deaths were elderly patien with severe underlying diseases. SARI has caused global concern

Statistics of the 41 patients with SARI published in JAMA initially s patients were transferred into the ICU, of which 11 (85%) had ARD had shock. Of these, 10 (77%) required mechanical ventilation sup (15%) required ECMO support. Of the above 13 patients, 5 (38%) and 7 (38%) were transferred out of the ICU. Viral pneumonia is a condition with a poor clinical prognosis. For most viral infections, t effective targeted antiviral drugs, and symptomatic supportive trea current main treatment.

Vitamin C, also known as ascorbic acid, has antioxidant properties happens, the cytokine surge caused by sepsis is activated, and ne lungs accumulate in the lungs, destroying alveolar capillaries. Early have shown that vitamin C can effectively prevent this process. In vitamin C can help to eliminate alveolar fluid by preventing the acti accumulation of neutrophils, and reducing alveolar epithelial water damage. At the same time, vitamin C can prevent the formation of extracellular traps, which is a biological event of vascular injury ca neutrophil activation. Vitamins can effectively shorten the duration cold. In extreme conditions (athletes, skiers, art workers, military e effectively prevent the common cold. And whether vitamin C also h protective effect on influenza patients, only few studies have show deficiency is related to the increased risk and severity of influenza controlled but non-randomized trial, 85% of the 252 students treat a reduction in symptoms in the high-dose vitamin C group (1g / h a of symptoms for 6h, followed by 3 * 1g / day). Among patients with ARDS, patients in the high-dose vitamin group did not show a bett and other clinical outcomes. There are still some confounding fact existing research, and the conclusions are different.

Therefore, during the current epidemic of SARI, it is necessary to s efficacy and safety of vitamin C for viral pneumonia through rando 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: Vit C 24g Vitamin C will be infused in the experimental group per da by the infusion pump with a speed of 7ml/h. Other Name: Vitamin C • Drug: Water for infusion 50ml water for infusion will be infused in the placebo compara per day for 7 days by the infusion pump with a speed of 7ml/h
Study Arms ICMJE	• Experimental: Vit C 24g Vitamin C+water for injection, total volume 50ml. 7ml/h; in pump. Intervention: Drug: Vit C • Placebo Comparator: Water for injection 50ml water for injection. 7ml/h; infusion pump. Intervention: Drug: Water for infusion
Publications *	*Not Provided*

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

Recruitment Information

Recruitment Status ICMJE	Not yet 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 m
Eligibility Criteria ICMJE	Inclusion Criteria: 1. ≥ 18 years old; 2. Diagnosed as serious or critical SARI (according to the 4th v Diagnosis and Clinical management of 2019-nCoV infected p 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 tl 6. Previously complicated with end-stage lung disease, end-sta glucose-6-phosphate dehydrogenase deficiency, diabetic ke active kidney stone disease; 7. The patient participates in another clinical trial at the same ti
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@

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
PRS Account	Zhongnan Hospital
Verification Date	February 2020

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