Use of Ascorbic Acid in Patients With COVID 19

ClinicalTrials.gov Identifier: NCT04323514

Recruitment Status : Recruiting
First Posted : March 26, 2020
Last Update Posted : March 26, 2020

See Contacts and Locations

Sponsor:
University of Palermo

Information provided by (Responsible Party):
Salvatore Corrao, MD, University of Palermo

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

Study Description

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Brief Summary:

Different studies showed that ascorbic acid (vitaminC) positively affects the development and maturation of T-lymphocytes, in particular NK (natural Killer) cells involved in the immune response to viral agents. It also

contributes to the inhibition of ROS production and to the remodulation of the cytokine network typical of systemic inflammatory syndrome.

Recent studies have also demonstrated the effectiveness of vitamin C administration in terms of reducing mortality, in patients with sepsis hospitalized in intensive care wards.

Given this background, in the light of the current COVID-19 emergency, since the investigators cannot carry out a randomized controlled trial, it is their intention to conduct a study in the cohort of hospitalized patients with covid-19 pneumonia, administering 10 gr of vitamin C intravenously in addition to conventional therapy.

Condition or disease	Intervention/treatment	Phase
Hospitalized Patients With Covid-19 Pneumonia	Dietary Supplement: Vitamin C	Not Applicable

Detailed Description:

The Sars-COV-2, has spread all over the world, in two months after its discovery in China. Outbreaks have been reported in more than 50 countries with more than 118,223 confirmed cases and 4,291 deaths worldwide. In Italy, the scenario is progressively worsening with 8514 confirmed cases and 631 deaths at 10/3/2020.

Along with the spread of this new virus there has been an increase in the number of pneumonia identified with the term novel coronavirus (2019-nCoV)-infected pneumonia (NCIP), which are characterized by fever, asthenia, dry cough, lymphopenia, prolonged prothrombin time, elevated lactic dehydrogenase, and a tomographic imaging indicative of interstitial pneumonia (ground glass and patchy shadows).

Recent studies have shown the efficacy of vitamin C and thiamine administration in patients hospitalized for sepsis in the setting of intensive wards in terms of mortality reduction. The use of intravenously vitamin C arises from the experimental evidence of its anti-inflammatory and antioxidant properties. Vitamin C causes a greater proliferation of natural killers without affecting their functionality. Moreover, the vitamin C reduces the production of ROS (reactive oxygen species) that contribute to the activation of the inflammosomi and, in particular, the NLRP3 that affetcs the maturation and secretion of cytokines such as IL1beta and IL-18 that are involved in the inflammatory systemic syndrome that characterized sepsis. Vitamin C blocks the expression of ICAM-1 and activation of NFKappaB that are involved in inflammatory, neoplastic, and apoptotic processes by the inhibition of TNFalfa.

For this reason, the use of vitamin C could be effective in terms of mortality and secondary outcomes in the cohort of patients with covid-19 pneumonia.

In view of the emergency of SARS-VOC-2 and the impossibility of carrying out a randomized controlled study, it is their intention to conduct an intervention protocol (administration of 10 grams of vitamin C intravenously in addition to conventional therapy) involving the cohort of hospitalized patients with covid-19 pneumonia.

Methods:

An uncontrolled longitudinal study will be conducted at the Arnas Civico-di Cristina-Benfratelli National Relevance Hospital in Palermo. This study will include all patients consecutively hospitalized with positive swab test of SARS-CoV-2 and interstitial pneumonia or with interstitial pneumonia with indication of intubation. At the admission, data will be collected: personal and anamnestic information, clinical and laboratory findings such as Gender, Age, Ethnicity, Comorbidities, Drugs, blood urea nitrogen, Creatinine, Electrolytes, Blood cell count, Clearance of the lactates, PCR, PCT, SOFA score, liver function, Coagulation, Blood gas analysis, Systolic and Diastolic Blood Pressure, Sp02, Glycaemia, Body Mass Index (BMI). Length of hospital stay will be recorded. After written informed consent, 10 grams of vitamin C in 250 ml of saline to infuse at a rate of 60 drops / minute will be administered. In-hospital mortality, reduction of PCR levels > 50% in comparison with PCR levels at the admission within 72 hours after the administration, lactate clearance, length of hospital stay, resolution of symptoms, duration of positive swab (days). Resolution of the CT imaging will be analysed. Stata Statistical Software: Release 14.1. College Station, TX: StataCorp LP) was used for database management and analysis.

Study Design

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Study Type :
Interventional (Clinical Trial)

Estimated Enrollment :
500 participants

Intervention Model:
Single Group Assignment

Masking:
None (Open Label)

Primary Purpose:
Treatment

Official Title:
Use of Ascorbic Acid in Patients With COVID 19

Actual Study Start Date :
March 13, 2020

Estimated Primary Completion Date :
March 13, 2021

Estimated Study Completion Date :
March 13, 2021

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: Patients with COVID-19 pneumonia Consecutive patients with COVID-19 pneumonia admitted to ARNAS Civico-Di Cristina-Benfratelli, Palermo	Dietary Supplement: Vitamin C 10 gr of vitamin C intravenously in addition to conventional therapy.

Outcome Measures

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Primary Outcome Measures :

1. In-hospital mortality [Time Frame: 72 hours]

   Change of hospital mortality

Secondary Outcome Measures :

1. PCR levels [Time Frame: 72 hours]

   Reduction of PCR levels > 50% in comparison with PCR levels at the admission, within 72 hours after the administration

2. Lactate clearance [Time Frame: 72 hours]

   Change of the lactate clearance

3. Hospital stay [Time Frame: 72 hours]

   Change of hospital stay days

4. Symptoms [Time Frame: 72 hours]

   Resolution of symptoms (Fever, Cough, Shortness of breath or difficulty breathing)

5. Positive swab [Time Frame: 72 hours]

Change of duration of positive swab (nasopharynx and throat)

6. Tomography imaging [Time Frame: 72 hours]

   Resolution of tomography imaging (example, patches located in the subpleural regions of the lung)

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:

Child, Adult, Older Adult

Sexes Eligible for Study:

All

Accepts Healthy Volunteers:

No

Criteria

Inclusion Criteria:

- In case of doubt of interstitial pneumonia with indications for intubation
- Positive swab test of SARS-CoV-2
- Interstitial pneumonia
- Signature of informed consent

Exclusion Criteria:

- Unsigned informed consent
- Negative swab test of SARS-CoV-2

Contacts and Locations

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Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04323514***

Contacts

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Locations

Italy

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Sponsors and Collaborators

University of Palermo

Study Documents (Full-Text)

Documents provided by Salvatore Corrao, MD, University of Palermo:

Study Protocol, Statistical Analysis Plan, and Informed Consent Form [PDF] March 12, 2020

More Information

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Responsible Party:
Salvatore Corrao, MD, Professor, University of Palermo

ClinicalTrials.gov Identifier:
NCT04323514 History of Changes

Other Study ID Numbers:
3143

First Posted:

March 26, 2020 Key Record Dates

Last Update Posted:

March 26, 2020

Last Verified:

March 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 Salvatore Corrao, MD, University of Palermo:

pneumonia
covid-19
hospitalized patients
vitamin C

Additional relevant MeSH terms:

Pneumonia
Lung Diseases
Respiratory Tract Diseases
Respiratory Tract Infections
Vitamins
Ascorbic Acid
Micronutrients
Nutrients
Growth Substances
Physiological Effects of Drugs
Antioxidants
Molecular Mechanisms of Pharmacological Action
Protective Agents