World Federation of Ozone Therapy

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Valencia, April 6, 2020

To whom it may concern

And to the attention of

Mirza Aghei Vaihd

Object: **COVID19 and ozone therapy under WFOT Protocols**

Dear Dr Vaihd,

Following your exchange of information with Prof. Lamberto Re we accepted to share with you the WFOT protocols already submitted to Hospitals and other Centres treating patients suffering from COVID-19, and written by Prof. Silvia Menendez, Prof. Lamberto Re and me.

Following the most relevant papers published on international journals (references 1-24) our protocol described below was approved by some Ethic Committees including University of La Sapienza in Rome.

Furthermore, the first outcomes are indicative of positive effects either in the early or late phases of this infection, reducing the respiratory failure in a significant number of patients.

We confirm to you and to your co-workers our support in the case your Health Authorities will decide to start with a trial also in your Country.

Best regards,

Prof. Dr. José Baeza-Noci, MD, PhD, OS
Vice-President WFOT

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Protocol: Ozone for systemic diseases should be used in a systemic way[1]

Indirect Endovenous Administration (IEV). As ozone is a gas, it cannot be directly injected into the blood mainstream, to avoid gas embolism. Special medical devices allow ozone dissolve into the patients' blood risk free. For details on this technique, please read World Federation of Ozone Therapy - WFOT's book[2].

Based on the information from the three Chinese Hospitals [25,26,27] that are presently performing an official clinical trial and also on the protocol presented and pre-accepted in University Sapienza in Rome, the proposed treatment will be:

100-150 mL of blood and 100-150 mL of ozone gas at 30-35 µgr/mL concentration.

In-hospital patients: each 12 hours application for minimum 14 days.

Complementary treatments to ozone administration.
To help ozone effect, it is advisable although not mandatory, the administration during the ozone treatment of:

- Vitamin C: 3 gr each 12 hours, 6 hours after ozone administration. 1 gr each 12 hours is already standardized in Italy and Spain protocols for COVID19.

- Glutathione: 600 mg each 12 hours, 6 hours after ozone administration. This substance is administered because ozone effect is partially based on it and old patients may have a low blood glutathione level.

TRIAL DESIGN

Purpose:

1. Enhance respiratory function.
2. Stop the blood interleukin storm.
3. Limit patients needing ICU.
4. Shorten the time in hospital.

Inclusion criteria:

1. Confirmed patients (or legal guardian) sign a written informed consent form.
2. Aged from 18 to 80 years, male or female.
3. Patients with positive detection of 2019 Novel Coronavirus Pneumonia fluorescence RT-PCR in respiratory specimens or blood samples.
4. Mild ill and severe ill patients NOT IN ICU are grouped based on the "Handbook of COVID-19 prevention and Treatment"[28].

Exclusion criteria:

1. Patients who may be transferred to other hospitals that are not included in the trial within 72 hours.

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2. G-6PD defect (Major Favism).
3. Pregnancy, especially early pregnancy.
4. Patients who continually use immune suppressant, or are organ transplant recipients within 6 months.
5. Patients who are receiving other clinical trials.

Interventions:

WE PROPOSE RANDOMIZING the patients going for control and IEV groups:

1. Control group. 30 patients. Conventional treatment.
2. Mild ill patients: 15 patients. Conventional treatment + ozone protocol.
3. Severe patients: 15 patients. Conventional treatment + ozone protocol.

Outcomes:

Primary:

1. Chest CT or Xray: interstitial pattern.
2. Whole blood cell analysis: leucocytes recount.
3. Oxygenation index: SpO2.
4. Inflammation index: PCR, IL6. (optional: IL2, procalcitonin, ferritin, D-dimer)
5. Fever: axillary temperature.

Secondary:

1. Recovery rate.
2. Conversion rate of severe patients.
3. Mortality rate.

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