Oxygen-ozone therapy is a success for Covid-19 in Italy – 94% of non-intubated and 73% of intubated patients rapidly recover. By comparison, only 20% of NYC's intubated patients recover at all.

May 17, 2020. To study oxygen-ozone therapy for Covid-19, single and multicenter, randomized, controlled clinical trials (involving 800 patients and 26 hospitals) are currently underway in multiple countries including Italy [1,2], Spain [3,4], and China [5,6,7]. Meanwhile, the Italian Scientific Society of Oxygen-Ozone Therapy (SIOOT) has released 3 reports on hospitalized Covid-19 patients in Italy that show extremely promising results for oxygen-ozone therapy [8]. This document compiles these reports. To aid in interpreting the data, contextual information is also included, available from international press interviews of SIOOT's international president, Dr. Marianno Franzini, and others.

Background: Oxygen-ozone therapy is a proven, safe antiviral [9,10]. On March 24, 2020 the research wing of the Italian Ministry of Health, the Istituto Superiore di Sanità (ISS) approved the SIOOT's request to use oxygen-ozone therapy in Italian hospitals for Covid-19 patients [11]. The SIOOT is responsible for distributing required equipment, training doctors in their protocol, and reporting results to the ISS [12,18]. Currently more than 20 hospitals are using oxygen-ozone therapy, including in Rome, Milan, Vimercate, Bergamo, Naples, Udine, Foggia, Brescia, Parma, Palermo, Teramo, Lecco, Turin, Pavia, Lombardy, Piedmont, Emilia-Romagna, Veneto, and Lazio [13,14,15].

Comparative analysis shows promising results: The Italian data reports below show a significantly lower death rate for the oxygen-ozone group and rapid improvement compared to areas where oxygen-ozone therapy is not being utilized, such as NYC. Control data of blood biomarkers in Report 5 (below) also show broad beneficial effects.

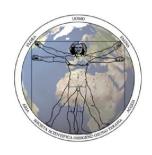
<u>Businessinsider.com</u> reports that in NYC 80% of intubated patients ultimately die [16]. Only 17% of intubated patients on oxygen-ozone therapy died. Similarly, <u>abc7.com</u> reports that NYC's intubated patients average 11-21 days to become extubated [17]. The oxygen-ozone group's extubates became so in only 5 days on average.

According to Dr. Luigi Valdenassi, national president of SIOOT and co-signer of the reports with Dr. Marianno Franzini, "the immediately detectable data is that oxygen ozone therapy, applied with the SIOOT protocol, is 100% effective on Covid patients in Phase 1 and 2, that is before intubation." Dr. Franzini added, "The 7 patients [out of 73 -- 4 intubated, 3 not] who had an unsuccessful outcome were in very serious condition, with bacterial superinfection, septic shock, pulmonary embolism and myocarditis, to the point that it was not even possible to subject them to the full cycle of oxygen-ozone. [The] 3 [non-intubated of the 7]...were in such critical condition that there was not even time to take them to intensive care." "This data confirms that, if ozone therapy was practiced on patients who are positive or have symptoms that are in isolation at home, oxygen-ozone...could eradicate the epidemic and safely restart economic activities," concluded Dr. Vandenassi [18].

Please note however, as reported by the <u>Wall Street Journal</u>, South Korean doctors believe Covid-19 can linger in the body long after symptoms subside, and may take weeks to months to fully clear [19]. The last line on the first Italian report below (Report 3) shows that 14% of the oxygen-ozone group test negative on a double swab test after only 5 days of treatments. Report 3 also states, "[95% of survivors] significantly improved." So why didn't they all test negative? It's possible improved-yet-still-positive patients are on a path to full recovery. Advanced cases with extensive viral progression could take longer. The various international clinical trials are tracking participants for 10-300 days and may clarify when one can expect the oxygen-ozone group to fully clear the virus.

Mechanisms of Action: In a peer-reviewed article, Dr. Robert Rowen and Dr. Howard Robins describe how ozone may inactivate coronavirus by oxidizing the cysteine on its spike proteins, in addition to "improving blood rheology, oxygen delivery, oxygen utilization, endothelial nitric oxide production, and immune modulation via cytokine induction" [20]. Additionally, Dr. Rodolfo Pizzuto Antinoro, a top Italian cardiologist who was Knighted by the Italian Republic explains, "Covid-19 kills because it causes a pulmonary embolism...[for which] forced ventilation has no effect because the peripheral vessels of the lung are closed and oxygen can not go into the blood. ...[So] you have to find a way to oxygenate the blood by bypassing the lungs. This is why major auto-hemo infusions with ozone [MAH] are made: to ensure that the blood is oxygenated efficiently and abundantly. ...When there is a shortage of oxygen in the blood, it happens that the heart, kidneys and brain enter a suffering condition that can generate irreversible damage." Dr. Pizzuto further specified that the therapeutic properties of ozone-oxygen are known and widely proven by the scientific literature [21].

Evidence suggests oxygen-ozone therapy could radically reduce Covid-19 deaths and suffering in as little as one week.



SIOOT

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ASSOCIATA FISM - FEDERAZIONE DELLE SOCIETÁ MEDICO-SCIENTIFICHE ITALIANE



[Translated from Italian]

THIRD REPORT ON THE USE OF OXYGEN-OZONE SIOOT IN 73 PATIENTS, FROM LESS SERIOUS TO MORE SERIOUS WITH COVID-19.
OF THESE, 61 PATIENTS SIGNIFICANTLY IMPROVED.

OF THESE, OF FATILITIES SIGNIFICANTET INFROVED.					
PATIENTS TREATED	73				
INTUBATED PATIENTS	24				
NON-INTUBATED PATIENTS	49				
AVERAGE OF 5 TREATMENTS OXYGEN-OZONE THERAPY					
EXTUBATED PATIENTS	15				
PATIENTS CURRENTLY INTUBATED	5				
PATIENTS WHO DID NOT NEED TO BE INTUBATED	36				
PATIENTS INTUBATED AND DECEASED FROM BACTERIAL	7				
SUPERINFECTION, SEPTIC SHOCK, PULMONARY					
EMBOLISM AND MYOCARDITIS (2 TREATMENTS)					
CURED PATIENTS WITH TWO NEGATIVE SWABS	10				

PLEASE NOTE: The immediately detectable data is that oxygen-ozone therapy SIOOT is indicated primarily in Phase 1 and 2 patients and before intubation. This data suggests that if the intervention was done at home it would be a success even greater than the current one.

It reconfirms what happened:

- 1. General improvement of clinical conditions
- 2. Normalization of body temperature
- 3. Reduction of PCR (C-reactive protein)
- 4. Normalization of heart rate
- 5. Improved oxygen saturation and reduced oxygen support
- 6. Normalization of renal function (creatinine)
- 7. Increased leukocytes and lymphocytes

Bergamo, 24/04/2020

Sharing clinical trial data is in everyone's interest: PATIENTS, CLINICS, REGULATORY AUTHORITIES

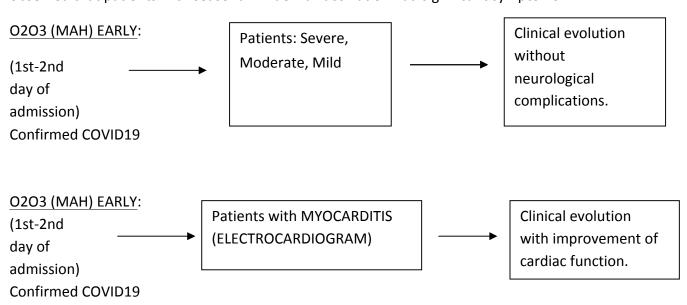
Prof. Luigi Valdenassi Presidente SIOOT Prof. Marianno Franzini Presidente SIOOT International [Translated from Italian] Hematoclinic examinations of 73 patients treated with oxygen-ozone therapy (O2O3) for Covid-19 via major auto-hemo infusion (MAH), provided by the San Carlo Clinic of Paderno Dugnano and the Hospital of Fidenza. Covid-19 patient values before and after 3-4 treatments on average are shown in detail.

No. Of Patients: 73 No. Of Treatments Per Patient: 3-4 28 April 2020

	Initial mean value	After 3-4 treatments with O2O3
Body temperature	99.86°- 101.66°	96.8° - 97.7°
Cardiac Fr	90 -100	70 - 75
S. O2: intubated	<70	intubated
S. O2: non-intubated	80 - 85	92 - 95
Blood Sugar	200 – 300	90 -150
Transaminase	90 – 250	40 - 50
Creatinine	1.5 – 3.5	1 – 1.3
Electrolytes: Na – K –Ca	< normal	normal
Leukocytes	3.000 - 4.000	>5.500
Lymphocytes	Very Severe <3	Very Severe < 7
	Severe <10	Severe 10 - 20
	Moderate 10 - 15	Moderate 15 - 20
	Mild 15 - 20	Mild 25 - 30
PCR (C-reactive protein)	10 – 200	<10
LDH	300 - 350	<250
D-dimer	600 - 2000	400 - 500
D-dimer > 3.000	8.000 - 15.000	Thromboembolism
Procalcitonin	< 0.5 ng/ml	<0,05
Procalcitonin	>5 ng/ml	Superinfection

Associated therapy: in the opinion of the Attending Physician

Observation: patients not treated with combined Ozonotherapy had a slower recovery. We observed that patients with seasonal influenza vaccination had significant symptoms.



O2O3 protocol: method as provided by SIOOT in 5 phases

O2O3 Materials:

- Multioxygen medical equipment 95 CPS
- SANO3 bag, certified

HEMATOCLINIC DATA DEMONSTRATES THE EFFECTIVENESS OF OXYGEN OZONE THERAPY (O2O3) WITH SIOOT PROTOCOL IN THE TREATMENT OF COVID19

•	Number of patients: 40			Number of patients: 40		
	PATIENTS TREATED WITH STANDARD THERAPY AND OXYGEN OZONE SIOOT			PATIENTS TREATED WITH ONLY STANDARD THERAPY		
	Initial mean value	After 3-4 O2O3 treatments	% Change	Initial mean value	Final value after 15 days	% Change
Body Temperature	101.66	97.7	-5%	101.48	100.22	-2%
Blood Sugar	300	150	-50%	171	134	-25%
Creatinine	3.5	1.3	-60%	1,27	1,50	+15%
Leukocytes	3000	5500	+80%	6379	8354	+31%
Lymphocytes ¹	15	30	+100%	15,48	21,38	+40%
PCR (C-reactive protein)	10	<10	-50%	7,46	5,97	-20%
D-dimer ²	1300	500	-54%	1020	939	-10%

¹ More lymphocytes means immune response / capacity

Associated therapy: in the opinion of the Attending Physician

Observation: patients not treated with oxygen ozone therapy had a slower recovery*1

EARLY 0203 (MAH): Patient: Severe Clinical evolution without (1st-2nd neurological complications. Moderate day of Unharmed Mild admission) Confirmed COVID19 EARLY O2O3 (MAH): Patients with PERICARDITIS / Clinical evolution with (1st-2nd **MYOCARDITIS** improvement of day of (forms of microvasculitis) cardiac function. admission) **ELECTROCARDIOGRAM** Confirmed COVID19

O2O3 protocol:

Method as provided by SIOOT in the 5 stages

Material O2O3:

Equipment with ozonation tubes of minimum length of 60 cm, A. T. Transformers producing at least 16,000 volts, oxygen flow variable from 1 to 10 lt.

SANO3 bag, specially certified phthalate-free

² Elevated D-dimer levels > risk of Pte (pulmonary embolism/Microthrombosis) > risk of death

^{* 1} Slower response and > late complications with metabolic syndrome (renal failure, microthrombosis, febrile)

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Multicenter. Randomized. Controlled. 90 Participants: phase 2-4, of 5 phases defined by Italian Society of Emergency and Urgency Medicine- SIMEU. 9 Locations: (1) Azienda Sanitaria-Universitaria Integrata di Udine, Italy; (2) Fondazione Toscana Gabriele Monasterio; (3) Policlinico Militare, Roma; (4) Ospedale San Liberatore di Atri; (5) Ospedale Umberto I di Torino; (6) Università di Siena; (7) Ospedale Civile di Lucca; (8) Ospedale di Siracusa; (9) Azienda Sanitaria Locale di Vercelli. Duration: 6 months, April 8, 2020 – Oct 8, 2020.

2. Clinical Trial - Italy (2020) Oxygen-Ozone as Adjuvant Treatment in Early Control of COVID-19 Progression and Modulation of the Gut Microbial Flora (PROBIOZOVID). Azienda Policlinico Umberto I, Rome, Italy. ClinicalTrials.gov Identifier: NCT04366089. https://www.clinicaltrials.gov/ct2/show/NCT04366089

Randomized. Controlled. 152 Participants: stages I, II, III as defined by the Italian Society of Anesthesia Analgesia Resuscitation and Intensive Care (SIAARTI). **Location:** Azienda Policlinico Umberto I, Rome, Italy. **Duration:** 10 months, March 26, 2020 - Dec 31, 2020.

3. Multicenter Clinical Trail (9 Centers) - Spain (2020) Ozone Auto-hemotherapy for COVID-19 Pneumonia (COVID-OZO). Institut d'Investigació Biomèdica de Girona Dr. Josep Trueta, Girona, Spain. <u>ClinicalTrials.gov</u> Identifier: NCT04370223. https://clinicaltrials.gov/ct2/show/NCT04370223

Multicenter. Randomized. Controlled. 208 Participants with confirmed severe acute respiratory syndrome and confirmed pneumonia. 9 Locations: (1) Hospital Universitari Dr Josep Trueta, Girona, Spain, 17007; (2) Clinica Nuestra Señora del Rosario, Ibiza, Spain; (3) Hospital Quirón Rey Juan Carlos I, Madrid, Spain; (4) Hospital Universitario 12 de Octubre, Madrid, Spain; (5) Hospital Universitario Infanta Leonor, Madrid, Spain; (6) Hospital Universitario Príncipe de Asturias de Alcalá de Henares, Madrid, Spain; (7) Fundació Althaia de Manresa, Manresa, Spain; (8) Spanish Society of Ozone therapy, Valencia, Spain; (9) Hospital Clínico Universitario de Valladolid, Valladolid, Spain. Duration: 7 months, May 4, 2020 - Dec 25, 2020.

4. Clinical Trial - Spain (2020) Indirect Endovenous Systemic Ozone for New Coronavirus Disease (COVID19) in Non-intubated Patients (OzonoCOVID19). Sociedad Española de Ozonoterapia. ClinicalTrials.gov Identifier: NCT04359303. https://clinicaltrials.gov/ct2/show/NCT04359303

Randomized. Controlled. 50 Participants: mild non-intubated only, as defined by WHO and Berlin Criteria. **Location:** Sociedad Española de Ozonoterapia, Valencia, Spain, 46013. **Duration:** 2-3 months, April - June 2020.

5. Multicenter Clinical Trial (4 Centers) - China (2020) A multicenter randomized controlled trial for ozone autohemotherapy in the treatment of novel coronavirus pneumonia (COVID-19). Tianjin Huanhu Hospital. www.chictr.org identifier: ChiCTR2000030102. http://www.chictr.org.cn/showproj.aspx?proj=49747

Multicenter. Randomized. Controlled. 180 Participants: common, severe, and critical NCP as defined by Pneumonitis Diagnosis and Treatment Scheme for Novel Coronavirus Pneumonia (Trial Version 6). 4 Locations: (1) Tianjin Huanhu Hospital, Tianjin, China; (2) Tianjin Haihe Hospital, Tianjin, China; (3) Zhongnan Hospital, Wuhan, Hubei, China; (4) Enshi Central Hospital, Enshi, Hubei, China. Duration: 3 months, Feb 24, 2020 – May 31, 2020.

- 6. Clinical Trial China (2020) A randomized controlled trial for the efficacy of ozonated autohemotherapy in the treatment of Novel Coronavirus Pneumonia (COVID-19). Union Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan. www.chictr.org identifier: ChiCTR2000030006. http://www.chictr.org.cn/showproj.aspx?proj=49737
 Randomized. Controlled. 60 Participants with chest CT confirmed pulmonary lesions and fever or respiratory symptoms. Location: Union Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan, Hubei, China. Duration: 3 months, Feb 19, 2020 May 19, 2020.
- 7. Clinical Trail China (2020) Clinical study for ozonated autohemotherapy in the treatment of Novel Coronavirus Pneumonia (COVID-19). Academy of Medical Engineering and Translational Medicine, Tianjin University, and Haihe Hospital, Tianjin University, Tianjin, China. www.chictr.org identifier: ChiCTR2000030165. http://www.chictr.org.cn/showproj.aspx?proj=49947

Non-random. Controlled._60 Participants: mild, sever, and critical as defined by 5th Ed. of Treatment and Diagnosis Plan of National Health Commission of Peoples Republic of China. **Location:** Haihe Hospital, Tianjin University, Tianjin, China. **Duration:** 10 months, Feb 22, 2020 – Dec 31, 2020.

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Note on safety: In 1982 Marie-Theres Jacobs did a large-scale safety study on oxygen-ozone therapy in Germany. She analyzed 384,775 patients. Each patient received multiple treatments. Over 5.5 million treatments were surveyed. An adverse side effect rate of only 0.0007% occurred. Oxygen-ozone therapy is extremely safe when used in the established concentrations and protocols. Please note: ozone is never to be breathed directly into the lungs.

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