



## ISCO3 Clinical Trials Follow-up on the preliminary results about the use of O<sub>2</sub>/O<sub>3</sub> in the treatment /prevention of Novel Coronavirus Pneumonia (COVID-19).

Country Region	Protocol	Remarks / Side effects
<b>BAZIL</b> Maria Emilia Gadelha Serra <b>RBR-5v3k5d emilia.gadelha1@gmail.com</b> Arnoldo de Souza <b>RBR-97nt6j arnoldos@cardiol.br</b>	Study of the use of ozone therapy adjunct to the treatment of Covid-19 infections Multicentre Study of the Integrative and Complementary Practice of the Use of Ozone Gas in Outpatients with Covid-19	<a href="http://www.ensaiosclinicos.gov.br/rg/RBR-5v3k5d/">http://www.ensaiosclinicos.gov.br/rg/RBR-5v3k5d/</a> Control 150 patients / Treatment 50 Patients (rectal ozone) <a href="http://www.ensaiosclinicos.gov.br/rg/RBR-97nt6j/">http://www.ensaiosclinicos.gov.br/rg/RBR-97nt6j/</a> Control 71 patients / Treatment 71 Patients (rectal ozone 30 µg/mL, max 240 mL)
<b>CHINA</b> Hospital / N patients = 4 FINISHED* Reg. <b>ChiCTR2000030102</b> Researcher: Huiling Huang. / Location: Tianjin Haihe <b>ChiCTR2000030165</b> Tianjin University <b>ChiCTR2000030006</b> Union Hospital	MAH 100 mL blood + 100 mL, up-to 200 mL, 1-2 times a day. Critical case 2-4 times a day. Time schedule: 10 d <b>Case report in Innovation (N Y).</b> 2020 Nov 25; 1(3): 100060. doi: 10.1016/j.xinn.2020.100060 Control group:30; mild ill patients:15; severe/critical ill patients:15;	Patient feels better // Chest tightness is improved ↑ 50 % PaO <sub>2</sub> after the first application <b>S.E.: Allergy</b>
<b>CUBA</b> Hosp. Dr. Salvador Allende, Sponsor: Dr. Rodolfo Suárez OZO-001 CNIC (Promotor). Inv. P. Zullyt Zamora R <b>RPCEC00000320</b> zullyt.zamora@enic.edu.cu	Rectal insufflation in SARS-CoV2 hosp. patients Rectal insufflation in SARS-CoV2 hosp. patients 16 Conventional Therapy / 16 Conventional plus O <sub>3</sub> rectal (20→40 µg/mL, vol 100 → 200 mL, one every 12 h, total 20 sessions)	↓ Viral Load in 5 days ↑ Clinic Improve clinicals symptoms and oxidative stress markets. ↓ Viral Load in 75% of patients in 6 days.
CNIC (Promotor). Inv. P. Zullyt Zamora R zullyt.zamora@cnic.cu <b>RPCEC00000341</b>	Prevalence of positive evolutive PCR in patients with COVID 19 treated with <b>rectal ozone therapy</b> : observational study prospective cohort.	
<b>INDIA</b> Dr Mili Shah <b>CTRI/2020/07/026354</b> <b>CTRI/2020/07/026671</b> <b>CTRI/2020/08/027038</b> Dr. Prabhat Kumar / Dr. Ashish	n=60 Rectal insufflation and minor auto haemotherapy together with standard of care. Outcome in: Int Immunopharmacol 2020 Dec 23;91:107301. doi: 10.1016/j.intimp.2020.107301. N=10 O <sub>3</sub> SS Dr Alok Sharma / Dr Mili Arpan / Dr Jignasha N=100 Study to assess effects of nano ozonised hydrogen peroxide nebulisation on results of RT-PCR for novel corona Virus thus infectivity and clinical course among mild to moderate sick COVID-19 Patients	There was improved SPO <sub>2</sub> , clinical symptoms status. There was faster viral eradication from host cells. 77% of subjects from the ozone-treated group were RT-PCR negative on day 5 and 100% subjects were RT-PCR negative on day 10. Manuscript on submission
<b>IRAN</b> <b>IRCT20191125045492N2</b> Bagheiat-allah Univ. of Med. Sci. Staff: Dr. Ali Sarrafzadeh/Dr. Izadi/Dr. Effat Nikfarjam <b>IRCT20200616047792N1</b> Behnam heibani behnamshei@gmail.com <b>IRCT20190618043923N4</b> NCT04400006	<b>Moderate</b> MAH 100-200 mL O <sub>3</sub> 1:1 35→45 µg/mL, daily 4 session <b>Severe</b> MAH 200 mL O <sub>3</sub> 1:1 35 →50 µg/mL daily 7 session <b>O<sub>3</sub> water 60 mL every 6 h</b> Ahvaz University of Medical Sciences	Preliminary results (n=14): Clinical improve. CT evidence of improvement Not yet recruiting <a href="http://en.irct.ir/trial/48978">http://en.irct.ir/trial/48978</a> Tabriz University of Medical Sciences
<b>ITALY</b> ClinicalTrials.gov <b>NCT04366089</b> N= 152 vs Control. Condition: Mild/Severe Researcher: Fabio Araimo Sponsor: Roberto Poscia M.D., Ph.D. Researcher: Amado del Monte / Carlo Tascini ClinicalTrials.gov Identifier: <b>NCT04388514</b> Z7C2CA5837. Location: Hosp. Univ. Santa M. Misericordia / Udine. EC Univ. Friuli Sponsor: Mariano Franzini // SIOOT Location: 17 Hosp.? N= 73	MAH Proportion of O <sub>2</sub> /O <sub>3</sub> : Blood 1:1. 250 mL O <sub>2</sub> /O <sub>3</sub> 30 µg/mL, every 12 h for 7 days. Location: Hosp. Umberto I. Roma Approval: Hosp. Umberto I/Univ. Sapienza Roma Proportion of O <sub>2</sub> /O <sub>3</sub> : Blood 1:1. MAH 200 mL. O <sub>2</sub> /O <sub>3</sub> 40 µg/mL, 3 times Groups: Antiretroviral therapy (AT) / or AT + O <sub>3</sub> N= 90 treated / two groups of 45 <b>Mild:</b> MAH blood: 150-200 mL 1:1 O <sub>3</sub> 30/ 40 µg/mL. 2 times a week. Ozonized oil spray 2 times a day. <b>Moderate:</b> MAH blood: 150-200 mL 1:1 O <sub>3</sub> 40/ 50 µg/mL. 3 times a week. Ozonized oil spray 2/3 times a day. Ozonized water 250 mL 3 times a day. <b>Severe / Critical:</b> S.E.: 1 death not associated with treatment septic shock	Prelim Result in: J Med Virol. 2020 Oct 28. doi: 10.1002/jmv.26636. Preliminary outcome: Clinical improvement in 35 /36 patients. Inter Emg Med 2020 Nov 1. doi: 10.1007/s11739-020-02542-6 ↑ PaO <sub>2</sub> , clinical symptoms, Renal function, Cardiac frequency, ↓ Fever, ↓PCR, removal of assistant respiration in 5 days. <i>International Immunopharmacology.</i> 2020 August 8, 88: 106879.
<b>NCT04651387</b> Efficacy and Safety of Ozonised Oil (HOO) in COVID-19 Patients (HOO-COVID)	<b>Licia Iacoviello, Neuromed IRCCS, Italy</b>	"HOO capsules" and "HOO oropharyngeal and nasal spray" will be administered 3 times per day and will be prescribed for 2 weeks (14 days).
<b>SPAIN</b> <b>EudraCT: 2020-002425-28</b> N= 50 Results available Sponsor: AEPROMO. Approved by etic committee 18/05/2020-05/20 ClinicalTrials.gov <b>NCT04359303</b> N=50 Dr. Javier H. Tallón, Univ. Cat. San A. Murcia ClinicalTrials.gov <b>NCT04370223</b> Researcher: Dr. Alberto Hernández N=10 Location: Hosp N. Señora del Rosario. Ibiza Institut d'Investigació Biomèdica de Girona Dr. Josep Trueta <b>NCT04444531</b>	O <sub>3</sub> SS 5→3 µg/kg b.w. a day x 10 days Vit.C + GSH 1,2 g i.v. in 100 mL Saline ↓ Fever in 3-4 days ↓ Viral Load in 3-4 days MAH O <sub>2</sub> /O <sub>3</sub> : Blood 1:1 200 mL O <sub>3</sub> 40 µg/mL + Base WHO recommended treatment. MAH O <sub>2</sub> /O <sub>3</sub> : Blood 1:1 200 mL 1:1 O <sub>3</sub> 40 µg/mL every 12 h for 5 day, 1 session a day up to 16 sessions. ? 18 participants. Ozone autohemotherapy plus standard treatment	Outcomes in: J Pharm Pharmacogn Res 9(2): 126–142. Not yet recruiting ↓ Ferritin ↓ d-dimer in 24/48 h ↑ Clinic. Am J Case Rep. 2020 Aug 17;21:e925849 International Immunopharmacology 2020 December 5, 90: 107261
<b>TURKEY</b> <b>Prevention</b> Sponsor: Marmara University // <b>NCT04400006</b> <a href="https://clinicaltrials.gov/ct2/show/NCT04400006">https://clinicaltrials.gov/ct2/show/NCT04400006</a> <b>Evaluation of Post-covid 19 Patients Who Receive Ozonotherapy With Thorax CT NCT04789395</b>	10 session in 6 months MAH O <sub>2</sub> /O <sub>3</sub> : Blood 1:1 100 mL O <sub>3</sub> 10 -20 µg/mL.71 participants. <b>Gaziosmanpaşa TREH Istanbul, Gaziosmanpaşa, Turkey</b>	Completed recruitment No Results Posted <b>Recruitment</b>

**Legend:** E.C., etic committee; S.E. side effects; IRB, Institutional Review Boards; FIO; New Italian Federation of Ozone Therapy; O3SS, ozonized Saline Solution; MAH, Mayor autohemotherapy; RIO3, rectal insufflation; SIOOT, Società Scientifica Ossigeno Ozono Terapia; AIRO, Accademia Internazionale di Ricerca in Ossigeno-Ozono Terapia. \* No more patients available, author will write a case report; ? Not confirmation available.